

ANNEX 4

Amendment to Seeds Regulation

The Food and Feed Regulation¹ introduces amendments to the Common Catalogue Directive² and the Vegetable Seed Directive.³ As a result of these amendments, it will be necessary to make consequential amendments to the Seeds (National Lists of Varieties) Regulations 2001 (the “National List Regulations.”)⁴ The effect of these amendments will be to provide as follows:

1. subject to paragraphs 2 and 3 below, a GM variety for use as food or feed or as a food or feed ingredient may only be accepted onto a National List if an authorisation has previously been obtained either:
 - (a) under Directive 90/220/EC⁵ or under Directive 2001/18/EC⁶ and under the Food and Feed Regulation; or
 - (b) solely under the Food and Feed Regulation, provided that an appropriate risk assessment has been carried out in accordance with that Regulation;
2. in order to be accepted onto a National List, a GM variety intended for use as food or as a food ingredient that obtained an authorisation under Directive 90/220/EC or Directive 2001/18/EC prior to 18th April 2004, must additionally have an authorisation issued under the Novel Foods Regulation;⁷
3. a GM variety intended for use as feed or as a feed ingredient, need not obtain an authorisation under the Food and Feed Regulation in order to be accepted onto a National List if, prior to 18th April 2004 it had obtained an authorisation under Directive 90/220/EC or Directive 2001/18/EC;
4. a GM variety for use **other than** as food or feed or as a food or feed ingredient may only be accepted onto a National List if an authorisation has previously been obtained either:
 - (a) under Directive 90/220/EC; or
 - (b) under Directive 2001/18/EC.
5. non-GM varieties within the scope of Regulation 258/97 must continue to have an authorisation issued under that Regulation before such varieties can be accepted onto a National List;
6. provision will be made to enable the national listing of a variety to be revoked where an authorisation issued under the relevant legislation is revoked or has otherwise expired; and

¹ Regulation 1829/2003 on genetically modified food and feed (O.J. L268, 18/10/03, p. 1).

² Directive 2002/53/EC on the common catalogue of varieties of agricultural plant species (O.J. L193, 20/07/2002, p. 1).

³ Directive 2002/55/EC on the marketing of vegetable seed (O.J. L193, 20/07/02, p. 33).

⁴ (S.I. 2001/3510).

⁵ Directive 90/220/EC on the deliberate release into the environment of genetically modified organisms (O.J. L117, 08/05/90, p. 15).

⁶ Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (O.J. L106, 17/04/01, p. 1).

⁷ EC Regulation 258/97 concerning novel foods and novel food ingredients (O.J. L43, 14/02/97, p. 1).

7. the provisions relating to records that must be kept and information that must be published by the Secretary of State will be amended to take account of these changes.

These consequential changes will be made as soon as possible.

Annex 5 – Consequential amendments to the Deliberate Release Directive 2001/18/EC

The Food and Feed Regulation⁸ introduces amendments to the Deliberate Release Directive.⁹ As a result of these amendments, it will be necessary to make consequential amendments to the Genetically Modified Organisms (Deliberate Release) (Scotland) Regulations 2002¹⁰ (the “Deliberate Release Regulations.”) The effect of these amendments will be to provide as follows:

1. that where products have been approved in accordance with legislative provisions other than those contained in the Deliberate Release Regulations, those products are only exempt from the requirements of sections 108(1)(a) and 111(1)(a) of the Environmental Protection Act 1990 if they have been marketed in accordance with any conditions or limitations imposed upon the consent that has been issued in relation to that product;
2. that genetically modified food and feed that has been authorised under the Food and Feed Regulation can be marketed without the need for a marketing consent under Part VI of the Environmental Protection Act 1990 if an environmental risk assessment has been carried out in accordance with article 5(5)(a) (food) or article 17(5)(a) (feed) of the Food and Feed Regulation; and
3. that, until 18th April 2007, the marketing of traces of a genetically modified organism or a combination of genetically modified organisms in products intended for direct use as food or feed or for processing is exempt from the requirement to obtain a marketing consent provided that the conditions specified in article 47 of the Food and Feed Regulation are met.

These consequential changes will be made as soon as possible.

It is proposed that the amending Regulations will also make provision to update references to relevant EC legislation and to clarify that Scottish Ministers must not grant or refuse to consent to release genetically modified organisms before the end of the latest date on which the representations and comments mentioned in regulation 20(f) of the 2002 Regulations can be made

⁸ Regulation 1829/2003 on genetically modified food and feed (O.J. L268, 18/10/03, p. 1).

⁹ Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (O.J. L106, 17/04/01, p. 1).

¹⁰ S.S.I. 2002/541