EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations, which apply only to Wales, implement Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC ("the Deliberate Release Directive"). They revoke the Genetically Modified Organisms (Deliberate Release) Regulations 1992 (S.I. 1992/3280) and make amendments to Part VI of the Environmental Protection Act 1990 ("the 1990 Act"). The Regulations are divided into nine parts and have five Schedules.

The subject matter of the Directive and its predecessor is the control of the deliberate release into the environment and the marketing of genetically modified organisms by means of the imposition of a requirement to obtain consent for those activities and to comply with the conditions imposed on the consent. The changes introduced by the Directive strengthen the existing control regime, particularly in respect of post marketing monitoring.

Directive 1990/220/EEC was implemented partly by the (pre-existing) provisions of Part VI of the Act and partly by the Genetically Modified Organisms (Deliberate Release) Regulations 1992.

These Regulations apply in relation to Wales the amendments made to the Act by the Genetically Modified Organisms (Deliberate Release) Regulations 2002 which are required to implement the Directive. They also revoke the 1992 Regulations.

The statutory basis for the requirement to obtain consent for the release or marketing of genetically modified organisms is section 111(1) of the Act. The cases and circumstances in which consent is required are prescribed in these Regulations. A general requirement to obtain consent for the release or marketing of genetically modified organisms is imposed by regulation 9 (for release) and regulation 15 (for marketing). This general requirement is subject to the exemptions provided for in regulations 10 (for release) and 16 (for marketing).

The definitions used in the provisions relating to the control regime are contained in sections 106, 107 and 127(1) of the Act. Regulations 4 and 5 amend a number of these definitions to reflect the Directive. Regulation 4 also amends the power in section 106 for the National Assembly for Wales to prescribe techniques which result in organisms becoming "genetically modified". However, on coming into force of these Regulations, references in the Act to "genetically modified organisms" will be interpreted by reference to the modification techniques described in regulation 6.

Parts II and III of the Regulations impose requirements for applications for consent to release and market, respectively, genetically modified organisms (including transitional provisions).

Part IV lays down the procedure for dealing with applications from their receipt to their determination (and, in the case of consents to release, their subsequent variation or revocation). For release consents this includes provisions for public consultation and for marketing consents (and renewals of such consents) their agreement at European Community level.

Part V includes general requirements for marketing consents and amends section 112 of the Act (which imposes conditions on consents). It also provides for what should happen when new information becomes available which affects the risk assessment for the marketing of a genetically modified organism.

Part VI supplements section 110 of the Act insofar as it allows action to be taken to prohibit the marketing of a genetically modified organism which has consent so as to bring it into line with the taking of "safeguard action" under the Directive.

Part VII prescribes additional categories of information to be made public, notwithstanding that they may be commercially confidential, for the purposes of section 123(7) of the Act.

Part VIII includes the requirement for different categories of information to be included in the public register to be kept by the National Assembly for Wales under section 122 of the Act.

Part IX includes a requirement for the National Assembly for Wales to take the precautionary principle into account in carrying out its functions under the Act and these Regulations. The "precautionary principle" is a term derived from Article 174 of the Treaty Establishing the European Community. The preamble to the Directive states that the principle must be taken into account in the implementation of the Directive.

Schedule 1 sets out the information to be included in applications for consent to release or market genetically modified higher plants.

Schedule 2 sets out the information to be included in applications for consent to release or market genetically modified organisms other than genetically modified higher plants.

Schedule 3 sets out the information to be included in an application for consent to market genetically modified organisms.

Schedule 4 sets out the information to be included in an assessment report.

Schedule 5 specifies the Regulations revoked by these regulations.

A regulatory appraisal has been prepared for these regulations and is available on the National Assembly for Wales web-site (www.wales.gov.uk). Copies can be obtained from the Welsh Assembly Government, Plant Health and Biotechnology Branch, Crown Buildings, Cathays Park, Cardiff, CF10 3NQ.