EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations, which are made under section 2(2) of the European Communities Act 1972, implement in Great Britain Council Directive 91/414/EEC (OJNo. L230, 19.8.91, p.1 to be read with corrigenda published in OJ No. L170, 25.6.92, p.40) concerning the placing of plant protection products on the market ("the Directive"), Commission Directive 93/71/EEC (OJ No. L221, 31.8.93, p.27), Commission Directive 94/37/EEC (OJ No. L194, 29.7.94, p.65), and Commission Directive 94/79/EC (OJ No. L354, 31.12.94, p.16), each of which amends Annexes II and III to the Directive, and Council Directive 94/43/EEC (OJ No. L227, 1.9.94, p.31) which establishes Annex VI to the Directive.

Directives 91/414/EEC and 93/71/EEC were extended to the European Economic Area ("the EEA") by Decision No. 7/94 of the EEA Joint Committee (OJ No. L160, 28.6.94, p.1), which amended the European Economic Area Agreement (see Decision 94/1 ECSC, EEC; OJ No. L1, 3.1.94, p.1).

The Directive (as extended to the EEA) establishes an authorisation system whereby plant protection products (defined in the Directive as active substances and preparations containing one or more active substances intended *inter alia* to protect plants against harmful organisms) may not be placed on the market and used in the territory of an EEA State unless they have been authorised under the Directive by that EEA State (or, subject to qualifications, by another EEA State). The Directive (as read with adaptations set out in Decision No. 7/94 of the EEA Joint Committee) establishes uniform rules on the conditions and procedures for authorisation, including rules on the mutual recognition of authorisations between EEA States. The purpose of the system is to ensure that wherever they are placed on the market and used within the EEA plant protection products are effective without causing harm to human or animal health and without adversely affecting plants and ground water or the environment in general.

Before a plant protection product can receive a standard authorisation all its active substances must be included in Annex I to the Directive although the Directive allows provisional authorisation of a product in advance of such inclusion.

The inclusion of active substances which were on the market of EEA States on or before 26th July 1993 (or, as far as Austria, Finland, Iceland, Norway, Sweden and, in so far as Liechtenstein is an EEA State, Liechtenstein are concerned, on or before 1st July 1994) are subject to a rolling review programme operated by the European Commission in conjunction with the member States of the European Community, although in transitional provisions set out in the Directive EEA States are permitted to authorise the placing on the market of products containing such substances until they have been reviewed; whereas inclusion of a new active substance in Annex I requires an application by the person intending to place it on the market.

The Directive also permits authorisations for short periods in the event of emergency and authorisations for releasing plant protection products into the environment for trial purposes. Authorisations are for fixed periods and in the case of standard authorisations they may be renewed on expiry. They may also be modified, or their range of application may be extended, in certain circumstances. Authorisations are subject to special requirements and conditions determined by the EEA State granting the authorisation, the breach of which would occasion automatic revocation. Authorisations carry a general requirement to notify the authorising EEA State of new information on the potentially dangerous effects of the authorised plant protection product or of residues of its active substances.

The Directive additionally provides certain data protection and confidentiality safeguards for holders of authorisations (whilst providing in certain circumstances for the release of information to other applicants and for the inspection of information by the public) and makes provision for the sharing of information between applicants and holders of previous authorisations of the same plant protection products with a view to limiting the duplication of tests on vertebrate animals. In addition, it prescribes requirements for labelling and packaging with which plant protection products must comply if they are to be placed on the market in the territory of an EEA State.

The Regulations incorporate the provisions of the Directive described above by providing for the establishment of the authorisation system in Great Britain, under the operation of the Minister of Agriculture, Fisheries and Food and the Secretary of State jointly ("the Ministers"). In the Regulations authorisations are described as approvals. The Regulations impose a prohibition on the placing on the market and use of plant protection products unless they have been approved by the Ministers under the Regulations and are placed on the market and used in accordance with any conditions or requirements specified in their approval (regulation 3(1) and (2)). Persons intending to place new active substances on the market must apply to the Ministers for such substances to be included in Annex I (regulation 3(3) and 4(1)).

Applications for standard, provisional and emergency approvals of plant protection products and applications for approval of plant protection products already authorised under the Directive for use in another EEA State are made to the Ministers by the persons responsible for first placing the products on the market in Great Britain (regulations 5 to 8, 11 and 13). Similarly, applications for approvals for trial purposes are made to the Ministers (regulation 9). The provisions of the Directive concerning extensions of the range of application of approved plant protection products and the provisions requiring the notification of potentially dangerous effects of approved plant protection products are respectively incorporated in regulations 10 and 14.

The data protection, information-sharing and confidentiality provisions of the Directive are set out in regulations 15, 16 and 17 and Schedule 1 and the provisions concerning the labelling and packaging of plant protection products are set out in regulations 18 and 19 and Schedule 2.

The Regulations confer enforcement powers on officers (who for specified purposes may be officers of local authorities) authorised by either of the Ministers, including powers to seize and dispose of plant protection products in the event of a breach of a prohibition, requirement or condition imposed by or under the Regulations, to enter on land and to effect certain other controls (regulations 20 and 24). The Regulations make such breaches a criminal offence (see regulations 3, 5, 7, 8, 9, 10, 11, 14, 16, 18 and 19), create certain other types of offence (regulation 21) and prescribe penalties and defences (regulations 22 and 23).

The transitional provisions and those specifying the extent to which the Control of Pesticides Regulations 1986 (S.I.1986/1510) will continue to apply are contained in regulations 26 and 27 and Schedule 3.

A compliance cost assessment has been prepared and a copy has been placed in the library of each House of Parliament. Copies of the compliance cost assesment and of a list of competent authorities of the member States of the European Community, to whom certain information and documents are required under the Regulations to be forwarded, can be obtained from the Pesticides Safety Directorate of the Ministry of Agriculture, Fisheries and Food, Room 308, Mallard House, Kings Pool, 3 Peasholme Green, York YO1 2PX.