EXPLANATORY NOTE

(This note is not part of the Regulations.)

1. These Regulations have effect with a view, first, to enabling applications to be made for agreement at Community level that an active substance can be used in a biocidal product and, secondly, to authorising the placing on the market and use of biocidal products to which these Regulations apply.

2. These Regulations—

(i) with the exception of regulation 42(2), implement as regards Northern Ireland Directive 98/8 of the European Parliament and the Council of 16th February 1998 concerning the placing of biocidal products on the market (O.J. No. L123, 24.4.98) ("the BP Directive"); and,

(ii) by regulation 42(2), implement as regards Northern Ireland Commission Directive 2000/21/EC (O.J. No. L103, 28.4.2000, p. 70) concerning the list of Community legislation referred to in the fifth indent of article 13(1) of Council Directive 67/548/EEC (O.J. No. 196, 16.8.1967, p. 1) (O.J./SE 1967 p. 234) ("the 2000 Directive").

Schedule 1 to these Regulations is based on Annex V of the BP Directive.

The principal provisions are as follows.

3. These Regulations do not apply to certain biocidal products nor to the carriage of biocidal products by rail, road, inland waterway, sea or air (*regulation 3 and Schedule 2*).

4. A person shall not place on the market a new active substance for use in a biocidal product unless an application to the Health and Safety Executive for Northern Ireland ("the Executive") or (under the Great Britain Regulations) to the Ministers, or to a competent authority of a member State of the Communities other than the United Kingdom has been made for inclusion of that new active substance in Annex I, IA or IB of the BP Directive. An application to the Executive must be accompanied by dossiers containing information which the Executive must evaluate, following which it must recommend to the European Commission whether or not an active substance should be included in Annex I, IA or IB of the BP Directive (*regulations 4, 5 and 6*). (The terms "active substance", "biocidal product", "competent authority", "the Executive", "the Great Britain Regulations", "the Ministers", "new active substance" and "place on the market" are defined in regulation 2(1).

5. A person shall not place on the market or use a biocidal product unless that biocidal product has been authorised in accordance with the provisions of these Regulations or the Great Britain Regulations. Where a biocidal product is a low-risk biocidal product, then a registration is required. Where a biocidal product contains an active substance which is included in Annex IB of the BP Directive then that biocidal product may only be used in a particular manner (*regulation 8*). (The term "low-risk biocidal product" is defined in regulation 2(1)).

6. To obtain an authorisation or a registration under these Regulations, a person must submit an application to the Executive together with the information specified in the Regulations. The Executive may grant a mutual authorisation or registration where another member State has granted an authorisation or a registration in respect of the same biocidal product and the Executive may also grant provisional authorisations and registrations. An authorisation and a registration may be granted subject to conditions (*regulations 9 to 14*).

7. The Executive may grant an emergency authorisation where such authorisation appears necessary because of an unforeseen danger (*regulation 15)*.

8. Provision is made for a biocidal product to be placed on the market for use in tests and experiments, including those involving the release into the environment of a biocidal product (*regulations 16 and 17*).

9. The Executive may revoke an authorisation or a registration in certain circumstances. It may also modify the conditions of use subject to which an authorisation or a registration is granted and review an authorisation or a registration (*regulations 19 and 20*).

10. Provision is made requiring a person to whom an authorisation or a registration has been granted to notify the Executive of information of which he is aware relating to the biocidal product in question (*regulation 21*).

11. The Executive may prohibit or restrict the sale or use of a biocidal product if it considers that the biocidal product constitutes an unacceptable risk to human or animal health or to the environment (*regulation 22*).

12. The Executive shall not make use of information submitted to it under the Regulations except in certain circumstances. A person providing information to the Executive may claim confidentiality in respect of that information if he considers that disclosure might harm his industrial or commercial position (*regulations 23, 24 and 26*).

13. Provision is made for co-operation between applicants for, and the holders of, authorisations or registrations regarding information relating to biocidal products. Provision is also made for the exchange of information between the Executive and the European Commission and the competent authorities in other member States (*regulations 25 and 28*).

14. The person responsible for first placing a biocidal product on the market is responsible for providing information to the Poisons Information Service. The information may only be disclosed for the purposes of medical treatment of a person affected by the biocidal product (*regulation 29*).

15. The Regulations impose obligations concerning the packaging, labelling and advertisement of a biocidal product (*regulations 30, 31 and 33*).

16. An application for an authorisation or a registration of a biocidal product is to be made by, or on behalf of, the person who first places the biocidal product on the market. An applicant must have a permanent office within the Community and the application must be in English (*regulation 34*).

17. The Executive must ensure that a file is kept in respect of every application for an authorisation or a registration made under the Regulations (*regulation 35*).

18. There is a right of appeal for any person aggrieved by certain decisions of the Executive made under the Regulations (*regulation 36*).

19. Provision is made for the enforcement of the Regulations, for the payment of fees and for transitional measures (*regulations 38, 39 and 41 and Schedules 10, 11 and 13*).

20. Regulation 42(2) amends the Notification of New Substances Regulations (Northern Ireland) 1994 (S.R. 1994 No. 6) by amending the disapplication in respect of plant protection products to include pesticides and adding a disapplication in respect of biocidal products, thereby implementing the 2000 Directive.

21. In Great Britain the corresponding Regulations are The Biocidal Products Regulations 2001 (S.I. 2001/880) and the Notification of New Substances (Amendment) Regulations 2001 (S.I. 2001/1055). The Great Britain Health and Safety Executive has prepared a regulatory impact assessment in respect of those Regulations and a copy of that assessment, together with a Northern Ireland supplement prepared by the Health and Safety Executive for Northern Ireland, is held at the offices of that Executive at 83 Ladas Drive, Belfast BT6 9FR from where copies may be obtained.