STATUTORY RULES OF NORTHERN IRELAND

2001 No. 422

Biocidal Products Regulations (Northern Ireland) 2001

Part IV

Use of Information

Co-operation in the use of information

25.—(1) Subject to paragraph (2), the Executive may give its consent to a new applicant referring to the information contained in the dossiers included in the application submitted to the Executive in respect of an approved biocidal product.

(2) The Executive shall not give its consent under paragraph (1) unless—

(a) the new applicant can provide evidence to the satisfaction of the Executive that—

(i) the biocidal product to which his application relates is sufficiently similar to, and

(ii) the active substance contained in that biocidal product is the same as that contained in,

the approved biocidal product, including in relation to the degree of purity and the nature of the impurities; and

(b) the information referred to in paragraph (1) is information—

(i) in respect of which the new applicant has a letter of access, or

(ii) which the Executive already holds and, by virtue of regulation 23 or 24, is entitled to use for the benefit of that new applicant.

(3) Notwithstanding the obligations contained in these Regulations to submit dossiers in support of an application for the authorisation of a biocidal product under regulation 9, 11, 13 or 17, or the registration of a biocidal product under regulation 10, 12 or 14, before carrying out an experiment on vertebrate animals, a new applicant shall ask the Executive—

(a) whether an authorisation or registration has been granted under these Regulations in respect of a biocidal product similar to that which the new applicant intends to use in such an experiment (whether or not that authorisation or registration has been revoked); and

(b) for the name and address of the authorisation holder in respect of that biocidal product.

(4) When a new applicant makes an enquiry pursuant to paragraph (2), he shall provide evidence that—

(a) he intends to apply on his own behalf for an authorisation of a biocidal product under regulation 9, 11, 13 or 17 or a registration of a biocidal product under regulation 10, 12 or 14; and

(b) the other information, which he has to provide with such an application in accordance with these Regulations, is available.

(5) If the Executive is satisfied that the new applicant intends to apply for an authorisation or a registration referred to in paragraph (4)(a), it shall provide him with the name and address of the

authorisation holder and shall inform the authorisation holder of the name and address of the new applicant.

(6) The authorisation holder and the new applicant shall take all reasonable steps to reach agreement on the sharing of information in order to avoid, if possible, the duplication of testing on vertebrate animals.

(7) The Executive shall encourage the authorisation holder to co-operate in the provision of information, with a view to limiting the duplication of testing on vertebrate animals.

(8) In this regulation—

(a) "approved biocidal product" means a biocidal product which has been authorised under regulation 9, 11 or 13 or registered under regulation 10, 12 or 14;

(b) "authorisation holder" means the person to whom—

(i) an authorisation of a biocidal product has been granted under regulation 9, 11, 13 or 17, or

(ii) a registration of a biocidal product has been granted under regulation 10, 12 or 14,

as the case may be;

(c) "dossier" includes a summary of a dossier;

(d) "new applicant" means a person who intends to apply for an authorisation or registration of a biocidal product under these Regulations.