
STATUTORY RULES OF NORTHERN IRELAND

2005 No. 526

Plant Protection Products Regulations (Northern Ireland) 2005

Duplication of experiments

16.—(1) Without prejudice to regulations 5(4) or 11, where an active substance has been included in Annex I—

- (a) any person who intends to apply for approval under regulation 5 or 7 of a plant protection product containing that substance, and who intends to use that plant protection product in an experiment involving vertebrate animals, shall enquire of the Department—
 - (i) whether approval has already been granted for that plant protection product and, if so,
 - (ii) as to the name and address of any holder of a previous or existing approval,and shall supply evidence that he intends to apply for approval on his own behalf and that the other information specified in regulation 5(4) is available;
- (b) the Department, if satisfied that that person intends to make such an application, shall provide him with the name and address of the holder or holders of previous or existing approvals and at the same time inform the holders of those approvals of the name and address of that person.

(2) The holder or holders of previous or existing approvals of a plant protection product and any person intending to make the application for an approval of the same product shall take all reasonable steps to reach agreement on the sharing of information so as to avoid the duplication of testing on vertebrate animals.

(3) Where a person requests any information with a view to inclusion of an old active substance in Annex I, the Department shall encourage holders of such information to co-operate in the provision of the requested information, with a view to limiting the duplication of testing on vertebrate animals.

(4) Where a person who intends to apply for approval of a plant protection product and holders of previous or existing approvals of the same product cannot reach an agreement on the sharing of information, the Department may give such directions about the sharing of the information to that person and those holders of previous or existing approvals located within Northern Ireland as appear to it to be necessary or expedient to avoid duplicate testing on vertebrate animals and such directions shall, in particular, determine both the procedure for utilising the information and the reasonable balance of the interests of the parties concerned.

(5) Any person who—

- (a) fails to make enquiries as required in paragraph (1)(a); or
- (b) fails to comply with a direction made by the Department under paragraph (4),

shall be guilty of an offence.

(6) Any person who causes or permits any person to—

- (a) fail to make enquiries as required in paragraph (1)(a); or
- (b) fail to comply with a direction made by the Department under paragraph (4),

shall be guilty of an offence.