STATUTORY RULES OF NORTHERN IRELAND

2001 No. 422

Biocidal Products Regulations (Northern Ireland) 2001

Part III

Biocidal Products

Mutual recognition of authorisations

11.—(1) Where a biocidal product has been authorised for placing on the market and use under the Directive in a member State, a person may apply to the Executive for authorisation of that biocidal product for placing on the market and use under this regulation.

(2) Subject to the following paragraphs and to regulations 18(3) and 39(2), within 120 days of the Executive receiving an application in accordance with this regulation, it shall authorise the biocidal product in question subject to the conditions and restrictions imposed on authorisation of that biocidal product in the member State where authorisation was first granted.

(3) Subject to paragraphs (8) and (9), the Executive shall not authorise a biocidal product under this regulation unless the following conditions are satisfied, namely—

(a) at least one of the active substances in the biocidal product is included in Annex I;

(b) any other active substances in the biocidal product are included in Annex I or Annex IA; and

(c) any requirements set out in Annex I or Annex IA relating to the active substance in the biocidal product have been fulfilled.

(4) Subject to paragraphs (8) and (9), the Executive shall not authorise a biocidal product under this regulation if it considers that—

(a) the biocidal product does not satisfy the requirements referred to in paragraphs 1(*a*)–(*d*) and 4(*b*) of Schedule 3; or

(b) the nature and quantity of—

(i) the active substance in,

(ii) where appropriate, any toxicologically or ecotoxicologically significant impurities and co-formulants in, or

(iii) the residues of toxicological or environmental significance which result from authorised uses of,

the biocidal product cannot be determined according to the relevant requirements in Annexes IIA, IIB, IIIA, IIIB, IVA and IVB.

(5) An applicant for authorisation of a biocidal product under this regulation shall submit with his application—

(a) a summary of the dossier submitted in support of the application for authorisation of that biocidal product in the member State in which the authorisation was first granted; and

(b) a certified copy of that authorisation.

(6) Where the Executive is satisfied that—

(a) the target species is not present in harmful quantities;

(b) there is unacceptable tolerance or resistance of the target organism to the biocidal product; or

(c) the relevant circumstances of use differ significantly from those in the member State where the biocidal product was first authorised, such that an authorisation without additional conditions may present unacceptable risks to humans, animals or the environment,

it may propose conditions and restrictions relating to the matters referred to in Schedule 5 concerning the placing on the market and the use of the biocidal product in addition to those conditions and restrictions imposed in the member State in which the biocidal product was first authorised.

(7) The additional conditions and restrictions proposed pursuant to paragraph (6) shall be such as to ensure—

(a) compliance with any requirements set out in Annex I or Annex IA relating to the active substance in the biocidal product in question; and

(b) that the requirements referred to in paragraphs 1(*a*)–(*d*) and 4(*b*) of Schedule 3 remain satisfied.

(8) Where, under this regulation, the Executive proposes to refuse to authorise a biocidal product or to impose conditions or restrictions in addition to those imposed in the member State in which the biocidal product was first authorised, it shall—

(a) notify the Commission, member States and the applicant; and

(b) provide the Commission, member States and the applicant with an explanatory document setting out—

(i) the name and specification of the biocidal product, and

(ii) the grounds on which it proposes to refuse authorisation, or to impose additional conditions or restrictions on authorisation.

(9) Where a Commission decision—

(a) confirms a proposed refusal, the Executive shall refuse to authorise the biocidal product in question;

(b) confirms any of the proposed additional conditions and restrictions, the Executive shall authorise the biocidal product in question subject to—

(i) the conditions and restrictions confirmed by the Commission decision, and

(ii) any conditions and restrictions imposed in the member State in which the biocidal product was first authorised;

(c) confirms that an authorisation, which the Executive proposes should be refused, should be granted, the Executive shall authorise the biocidal product in question subject to any conditions and restrictions imposed in the member State in which the biocidal product was first authorised;

(d) confirms that none of the additional conditions and restrictions proposed by the Executive should be imposed, the Executive shall authorise the biocidal product in question subject to any conditions and restrictions imposed in the member State in which the biocidal product was first authorised but without imposing the additional conditions and restrictions which it proposed.