STATUTORY RULES OF NORTHERN IRELAND

2001 No. 422

Biocidal Products Regulations (Northern Ireland) 2001

Part II

Active Substances

Applications for variation or renewal of the inclusion of active substances in Annex I, IA or IB

7.—(1) A person may apply to the Executive for a variation of the requirements subject to which an active substance was included in Annex I, IA or IB.

(2) Before the expiry of the initial period, or any renewed period, as the case may be, of the inclusion of an active substance in Annex I, IA or IB, a person may apply to the Executive, for the renewal of the inclusion of that active substance in Annex I, IA or IB for a period not exceeding 10 years.

(3) A person who applies to the Executive under paragraph (1) or (2) shall submit dossiers in accordance with regulation 5.

(4) Regulation 6(1) to (5) shall apply to an application made under paragraph (1) or (2) as it applies to an application made under regulation 5, save that—

(a) in the case of an application made under paragraph (1), the recommendation to be made under regulation 6(2)(*b*) shall be as to whether the variation should, or should not, be made; and

(b) in the case of an application made under paragraph (2), the recommendation to be made under regulation 6(2)(*b*) shall be as to whether the inclusion of the active substance in Annex I, IA or IB should, or should not, be renewed.

(5) Where there is a Commission decision that the Executive shall evaluate the dossiers submitted to a competent authority in support of an application for—

(a) a variation of the requirements subject to which an active substance was included in Annex I, IA or IB; or

(b) the renewal of the inclusion of an active substance in Annex I, IA or IB,

subject to regulation 39(2), within the period of 12 months of receiving the dossiers, the Executive shall comply with the requirements specified in paragraph (6).

(6) The requirements referred to in paragraph (5) are that the Executive shall—

(a) evaluate the dossiers;

(b) make a recommendation as to whether—

(i) the variation should, or should not, be made, or

(ii) the new active substance should, or should not, continue to be included in Annex I, IA or IB,

as the case may be; and

(c) send a copy of its evaluation and recommendation to the Commission, the member State and the applicant.

(7) Regulation 6(3) and (4) shall apply where the Executive evaluates dossiers under paragraph (6)(*a*) as if the dossiers had been submitted under regulation 5.