STATUTORY RULES OF NORTHERN IRELAND

2001 No. 422

Biocidal Products Regulations (Northern Ireland) 2001

Part III

Biocidal Products

Provisional registration

14.—(1) Subject to the following paragraphs of this regulation, the Executive may register, for a period not exceeding three years, a biocidal product for placing on the market and use which—

(a) contains a new active substance which is not included in Annex IA but in respect of which an application has been made to the Executive under regulation 5;

(b) does not contain a substance of concern;

(c) does not contain an active substance included in Annex I; and

(d) under the conditions under which that biocidal product may be used poses a low risk to humans, animals and the environment.

(2) The Executive shall not register a biocidal product under paragraph (1) unless—

(a) in accordance with regulation 6(2), it has evaluated the new active substance contained in that biocidal product which is not included in Annex IA and has recommended that the new active substance should be included in Annex IA; and

(b) the Executive has made the determinations referred to in Schedule 3.

(3) The Executive shall not register a biocidal product under paragraph (1) where—

(a) a member State has made an objection in accordance with Article 18(2) to the completeness of the dossiers submitted in support of the application under regulation 5; and

(b) that objection has been upheld by a Commission decision.

(4) The Executive shall not register a biocidal product under paragraph (1) where the new active substance contained in that biocidal product which is not included in Annex IA—

(a) is classified as carcinogenic, mutagenic, sensitising or toxic for reproduction; or

(b) is bioaccumulative and does not readily degrade.

(5) The Executive shall not register a biocidal product under paragraph (1) where the evaluation required by paragraph (2)(*a*) shows that—

(a) under normal conditions under which the new active substance may be used in the biocidal product, there are risks to the health of humans or animals or to the environment which give rise to concern; and

(b) there is another active substance included in Annex I for the same product-type which, having regard to current scientific and technical knowledge, presents significantly less risk than the new active substance to the health of humans or animals or to the environment

when used under normal conditions in biocidal products authorised in accordance with these Regulations, provided that—

(i) the chemical diversity of all the active substances included in Annex I is adequate to minimise the occurrence of resistance in organisms targeted by that biocidal product,

(ii) the Executive does not consider that it is necessary to acquire experience of using the new active substance in practice, and

(iii) the active substance included in Annex I can be used on the target organism with similar efficacy as the new active substance without significant economic and practical disadvantages for the user and without an increased risk to the health of humans or animals or to the environment.

(6) The Executive shall not register a biocidal product under paragraph (1) for use by the public, or for placing on the market for use by the public, where that biocidal product is classified as toxic or very toxic.

(7) Paragraphs (4)–(10) of regulation 10 shall apply in the case of an application for a registration granted under paragraph (1) as it applies in the case of an application for a registration granted under paragraph (1) of that regulation, and, in the application of this paragraph, a reference to a low-risk biocidal product in paragraphs (4)–(10) of regulation 10 shall be deemed to be a reference to a biocidal product.

(8) In a registration granted under paragraph (1), the Executive shall specify—

(a) the conditions and restrictions relating to the placing on the market and use of the biocidal product referred to in the registration necessary to ensure—

(i) compliance with any requirements which it has recommended should attach to the inclusion in Annex IA of the new active substance in the biocidal product, and

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

(b) any other conditions or restrictions subject to which the registration is granted.

(9) If, on the expiry of the period for which a registration has been granted under paragraph (1), a decision has not been taken concerning the inclusion in Annex IA of the new active substance in the biocidal product referred to in that registration, the Executive may register that biocidal product for placing on the market and use for a further period of one year.

(10) Paragraphs (2) to (8) shall apply to an application for a registration under paragraph (9) as they apply to an application for registration under paragraph (1).

(11) The Executive shall inform the Commission and the member States of every registration granted under paragraph (9).