STATUTORY RULES OF NORTHERN IRELAND

2001 No. 422

Biocidal Products Regulations (Northern Ireland) 2001

Part III

Biocidal Products

Authorisation of a biocidal product

9.—(1) Subject to the following paragraphs, the Executive may authorise a biocidal product for placing on the market and use for a period of time which ends on a date not later than the earliest date on which the entry in Annex I of any active substance in that biocidal product expires.

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

(a) the following conditions are satisfied, namely—

(i) at least one active substance in the biocidal product is included in Annex I at the time the authorisation is granted;

(ii) any other active substances in the biocidal product are included in Annex I or Annex IA at the time the authorisation is granted, and

(iii) any requirements set out in Annex I or Annex IA relating to the active substances in the biocidal product have been fulfilled; and

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

(3) The Executive shall not authorise 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—

(a) toxic;

(b) very toxic;

(c) carcinogenic category 1;

(d) carcinogenic category 2;

(e) mutagenic category 1;

(f) mutagenic category 2;

(g) toxic for reproduction category 1; or

(h) toxic for reproduction category 2.

(4) An applicant for the authorisation of a biocidal product under paragraph (1) shall submit his application to the Executive and with that application shall include—

(a) a dossier for that biocidal product satisfying, in the light of current scientific and technical knowledge—

(i) the requirements set out in Annex IVB where that biocidal product is a micro-organism, or

(ii) the requirements set out in Annexes IIB and IIIB where that biocidal product is not a micro-organism; and

(b) a dossier for each active substance in that biocidal product satisfying, in the light of current scientific and technical knowledge, the requirements of—

(i) Annex IVA, where the active substance in question is a micro-organism, and

(ii) Annexes IIA and IIIA, where the active substance in question is not a micro-organism.

(5) A dossier submitted in accordance with paragraph (4) shall include—

(a) a detailed and full description of any studies referred to in that dossier; and

(b) either—

(i) a detailed and full description of the methods used in carrying out such studies, or

(ii) a bibliographical reference to such methods.

(6) The information in dossiers submitted to the Executive in accordance with paragraph (4) shall be sufficient to enable the Executive to make the determination referred to in Schedule 3.

(7) The Executive—

(a) shall evaluate dossiers submitted in accordance with paragraph (4) in accordance with the common principles set out in Annex VI; and

(b) subject to regulations 18(3) and 39(2), shall decide without undue delay whether or not to authorise the biocidal product in question.

(8) If the evaluation of a dossier shows that additional information, which may include data and results from further testing, is necessary for the purpose of evaluating the risks of the biocidal product in question, the Executive shall request in writing the applicant to provide such additional information as it may specify.

(9) Where the Executive requests additional information under paragraph (8), the period of time within which the Executive shall decide whether or not to authorise the biocidal product in question shall not commence until the dossier is complete.

(10) In an authorisation granted under paragraph (1), the Executive shall specify—

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

(i) compliance with any requirements set out in Annex I or Annex IA relating to the active substance in that 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 authorisation is granted.

(11) The Executive may renew an authorisation granted under this regulation for a period of time which ends on a date not later than the earliest date on which the entry in Annex I of any active substance in the biocidal product the subject of the authorisation expires.

(12) Paragraphs (2) to (10) shall apply in the case of an application for the renewal of an authorisation under paragraph (11) as they apply in the case of an application for an authorisation under paragraph (1).

(13) Where an application for the renewal of an authorisation of a biocidal product granted under this regulation has been made, the Executive may, where necessary, renew that authorisation for such further period as is required to enable the Executive—

(a) to verify that the conditions specified in paragraph 2(*a*) continue to be satisfied; and

(b) to confirm, or otherwise, the determinations referred to in paragraph 2(*b*).