STATUTORY INSTRUMENTS

2001 No. 880

The Biocidal Products Regulations 2001

PART III

BIOCIDAL PRODUCTS

Registration of a low-risk biocidal product

10.—(1) Subject to the following paragraphs of this regulation, the Ministers may register a low-risk 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 IA of any active substance in that low-risk biocidal product expires.

(2) The Ministers shall not register a low-risk biocidal product under paragraph (1) unless—

(a) any requirements set out in Annex IA relating to the active substance in that low-risk biocidal product have been fulfilled; and

(b) the Ministers have made the determinations referred to in Schedule 3.

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

(4) Subject to paragraph (7), an applicant for the registration of a low-risk biocidal product under paragraph (1) shall submit his application to the Ministers and with that application shall include—

(a) a dossier containing the information set out in Schedule 4; and

(b) a dossier for each active substance in that low-risk 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 Ministers in accordance with paragraph (4) shall be sufficient to enable the Ministers to make the determinations referred to in Schedule 3.

(7) Where the applicant justifies the omission to the satisfaction of the Ministers, the applicant may omit from a dossier submitted in accordance with paragraph (4)(a) information which—

(a) is not necessary owing to the nature of—

(i) the low-risk biocidal product, or

(ii) its proposed uses;

(b) it is not scientifically necessary or technically possible to supply.

(8) The Ministers—

(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 regulation 39(2), shall decide within 60 days of their receiving an application whether or not to register the low-risk biocidal product in question.

(9) 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 low-risk biocidal product in question, the Ministers shall request in writing the applicant to provide such additional information as they may specify.

(10) Where the Ministers request additional information under paragraph (9), the period of time referred to in paragraph (8)(b) shall not commence until the dossier is complete.

(11) In a registration granted under paragraph (1), the Ministers shall specify—

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

(i) compliance with any requirements set out in Annex IA relating to the active substance in that low-risk 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.

(12) The Ministers may renew a registration 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 IA of any active substance in the low-risk biocidal product the subject of the registration expires.

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

(14) Where an application for the renewal of a registration of a low-risk biocidal product granted under this regulation has been made, the Ministers may, where necessary, renew that registration for such further period as is required to enable the Ministers—

(a) to verify that the requirements referred to in paragraph (2)(a) continue to be fulfilled; and

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