SCHEDULES

SCHEDULE 10

National homoeopathic products

Exceptions to requirement to submit safety data

4.—(1) The applicant does not need to submit data as to the safety of the product if—

(a) condition A, B or C is met; and

(b) the application is accompanied by a written statement that the condition is met.

(2) Condition A is that the product—

(a) is derived from a homoeopathic stock that is commonly present in food; and

(b) is intended to be administered orally.

(3) For this purpose "food" has the meaning given by Council Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety(**1**).

(4) Condition B is that—

(a) the product is derived from a homoeopathic stock from which is derived a medicinal product that has a marketing authorisation, certificate of registration or traditional herbal registration ("the source product");

(b) the source product is subject to general sale within the meaning of regulation 5(1); and

(c) the product has the same route of administration and the same degree of dilution as the source product.

(5) Condition C is that the product is derived from a homoeopathic stock that—

(a) is diluted to at least 1 in 10^{24} of the stock; and

(b) is not a material derived from a human or animal source.

(**1**) OJ No L 31, 1.2.2002, p.1, as last amended by Regulation (EC) No 596/2009 (OJ No L 188, 18.7.2009, p. 14).