SCHEDULE 1

AMENDMENTS TO SUBORDINATE LEGISLATION

Genetically Modified Organisms (Contained Use) Regulations (Northern Ireland) 2015

45.—(1) The Genetically Modified Organisms (Contained Use) Regulations (Northern Ireland) 2015(**1**) are amended as follows.

(2) In regulation 3(2)—

(a) in sub-paragraph (a)—

(i) in paragraph (ii) omit "or";

(ii) omit paragraph (iii);

(b) in sub-paragraph (b), for paragraph (i) substitute—

"(i) a medicinal product for veterinary use marketed in accordance with the Veterinary Medicines Regulations 2013(**2**);".

(3) After regulation 33 insert—

"**Transitional provision in relation to the withdrawal of the United Kingdom from the European Union**

33A.—(1) Subject to paragraphs (2) and (3), these Regulations do not apply to any activity which is covered by a written consent given by a competent authority of an EEA State in accordance with Article 15(3), 17(6) or 18(2) of Directive (EC) No 2001/18 of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms(**3**).

(2) The written consent referred to in paragraph (1) must be valid immediately before exit day.

(3) Any activity covered by the consent referred to in paragraph (1) must be conducted in accordance with any obligations, conditions or limitations attached to that consent.

(4) Subject to paragraphs (5) and (6), these Regulations do not apply to any genetically modified organisms which are cultured, stored, transported, destroyed, disposed of or used, where such organisms are, or are contained in, a medicinal product for human or veterinary use marketed in accordance with an authorisation under Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.

(5) The marketing authorisation referred to in paragraph (4) must be valid immediately before exit day.

(6) Any marketing authorisation referred to in paragraph (4) must be conducted in accordance with any obligations, conditions, restrictions, requirements or limitations attached to that authorisation."

(4) In Schedule 3, in paragraph 3 for sub-paragraph (d) substitute—

"(d) consideration of relevant legislation, including legislation on the protection of workers from risks related to exposure to biological agents at work, other classification

(**1**) S.R. 2015 No. 339.
(**2**) S.I. 2013/2033 amended by S.I. 2014/599, 2018/761.
(**3**) OJ No L 106, 17.04.2001, p. 1.

schemes referring to plant and animal pathogens, and other international and national classification schemes for genetically modified micro-organisms;".