DRAFT STATUTORY INSTRUMENTS

2019 No.

The Veterinary Medicines and Animals and Animal Products (Examination of Residues and Maximum Residue Limits) (Amendment etc.) (EU Exit) Regulations 2019

PART 4

Amendment and revocation of retained direct EU legislation

Commission Regulation (EU) 2018/782

10.—(1) Commission Regulation (EU) 2018/782 establishing the methodological principles for the risk assessment and risk management recommendations referred to in Regulation (EC) No 470/2009 is amended as follows.

(2) In Article 1—

(a) for "Agency" substitute "appropriate authority";

(b) for "preparing opinions on the" substitute "producing an assessment report in respect of".

(3) After Article 3, omit the words from "This Regulation" to "Member States".

(4) In Annex 1—

(a) in paragraph 1.1, for the words from "provisions related" to "Council" substitute "the Good Laboratory Practice Regulations 1999(**1**)";

(b) in paragraph 1.2, for "Directive 2010/63/EU of the European Parliament and of the Council" substitute "the Animals (Scientific Procedures) Act 1986(**2**)";

(c) in paragraph 1.7, in the second subparagraph—

(i) for "European Medicines Agency ('Agency')" substitute "appropriate authority";

(ii) for "the Agency" substitute "the appropriate authority";

(d) in paragraph 1.8, for the words from "the Agency's" to the end substitute "guidance issued by the appropriate authority";

(e) in paragraph 2.4.2(l), omit "Agency and other";

(f) in paragraph 2.4.2(m), for "Directive 2010/63/EU" substitute "the Animals (Scientific Procedures) Act 1986";

(g) in paragraph 2.6.1.3, for "Agency" substitute "appropriate authority";

(h) in paragraph 3.2.2(j), omit "Agency and other";

(i) in paragraph 3.2.2(k), for "Directive 2010/63/EU" substitute "the Animals (Scientific Procedures) Act 1986";

(j) in paragraph 3.5.5—

(**1**) S.I. 1999/3106, amended by S.I. 2004/994, 2005/2114, 2011/1043, 2018/378.
(**2**) 1986 c.14.

(i) for "Agency" substitute "appropriate authority";

(ii) for "European Reference Laboratory" substitute "relevant national reference laboratories";

(k) in paragraph 3.5.6—

(i) for "Agency's" substitute "appropriate authority's";

(ii) omit "other EU and";

(l) in paragraph 3.6.3 for "Agency's" substitute "the appropriate authority's".

(5) In Annex 2—

(a) in paragraph 2.1—

(i) in the second sentence, for the words from "the Agency's" to the end substitute "guidance issued by the appropriate authority";

(ii) in the third sentence, omit the words from "as defined" to the end;

(b) in paragraph 2.7.2, in the first sentence, for "Agency" substitute "appropriate authority".