STATUTORY INSTRUMENTS

2021 No. 904

The REACH etc. (Amendment) Regulations 2021

PART 2

Amendment of Regulation (EC) No 1907/2006

Amendment of Regulation (EC) No 1907/2006

2. Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)(**1**) is amended in accordance with this Part.

Article 3

3. In Article 3 (definitions), after paragraph 43 insert—

"**44.** relevant medical device: means a medical device within the scope of—

(a) the Medical Devices Regulations 2002(**2**);

(b) Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices(**3**) as it has effect in EU law; or

(c) Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices(**4**) as it has effect in EU law;

45. relevant accessory to a medical device: means an accessory to a medical device within the scope of—

(a) the Medical Devices Regulations 2002;

(b) Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices as it has effect in EU law; or

(c) Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices as it has effect in EU law."

Article 60

4. In Article 60(**5**) (granting of authorisations), in paragraph 2, for the words from "medical device" to the end substitute "relevant medical device".

(**1**) EUR 2006/1907.
(**2**) S.I. 2002/618, amended by S.I. 2003/1400, 1697, 2005/2759, 2909, 2007/400, 610, 803, 2008/530, 2936, 2009/383, 2010/557, 2012/1426, 2013/525, 2327, 2017/207, 2019/791.
(**3**) OJ No. L 117, 5.5.2017, p. 1, as last amended by Regulation 2020/561 (OJ No. L 130, 24.4.2020, p. 18).
(**4**) OJ No. L 117, 5.5.2017, p. 16, as last corrected by Corrigendum (OJ No. L 334, 27.12.2019, p. 167).
(**5**) Article 60(2) was amended by S.I. 2019/758.

Article 62

5. In Article 62(**6**) (applications for authorisations), in paragraph 6, for the words from "medical device" to the end substitute "relevant medical device".

Annex 12

6. In Annex 12 (general provisions for downstream users to assess substances and prepare chemical safety reports), in the introduction, in the fifth paragraph, for "Community" substitute "other".

Annex 14

7.—(1) In Annex 14 (list of substances subject to authorisation), entry 42 (4-(1, 1, 3, 3-Tetramethylbutyl)phenol, ethoxylated (covering well-defined substances and UVCB substances, polymers and homologues)) is amended in accordance with this regulation.

(2) In the entry for the column headed "latest application date", in point (b)—

(a) in the first indent—

(i) for "Directive 2001/83/EC" substitute "the Human Medicines Regulations 2012(**7**)",

(ii) before "medical devices", in the first place that it occurs, insert "relevant",

(iii) before "accessories" insert "relevant",

(iv) omit the words from "falling within" to "of the Council,";

(b) in the second indent—

(i) before "medical devices", in the first place that it occurs, insert "relevant",

(ii) before "accessories" insert "relevant",

(iii) omit the words from "falling within" to "2017/746,".

(3) In the entry for the column headed "sunset date", in point (b)—

(a) in the first indent—

(i) for "Directive 2001/83/EC" substitute "the Human Medicines Regulations 2012",

(ii) before "medical devices", in the first place that it occurs, insert "relevant",

(iii) before "accessories" insert "relevant",

(iv) omit the words from "falling within" to "2017/746,";

(b) in the second indent—

(i) before "medical devices", in the first place that it occurs, insert "relevant",

(ii) before "accessories" insert "relevant",

(iii) omit the words from "falling within" to "2017/746,".

Annex 17

8.—(1) Annex 17 (restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles) is amended in accordance with this regulation.

(2) In entry 51 (Bis(2-ethylhexyl) phthalate (DEHP) etc.)(**8**), in the second column, in paragraph 4(g)—

(**6**) Article 62(6) was amended by S.I. 2019/758.
(**7**) S.I. 2012/1916, amended by S.I. 2013/235, 1855, 2593, 2014/490, 1878, 2015/323, 570, 903, 1503, 1862, 1879, 2016/186, 190, 696, 2017/715, 1322, 2018/199, 378, 2019/62, 598, 703, 775, 1094.
(**8**) Entry 51 was amended by S.I. 2019/1144 as amended by S.I. 2020/1577.

(a) before "medical devices" insert "relevant";

(b) omit "within the scope of the Medical Devices Regulations 2002".

(3) In entry 68 (perfluorooctanoic acid)(**9**), in the second column—

(a) in paragraph 3(c)—

(i) after "2032 to" insert "relevant",

(ii) omit "within the scope of the Medical Devices Regulations 2002";

(b) in paragraph 4(d)(i)—

(i) after "implantable" insert "relevant",

(ii) omit "within the scope of the Medical Devices Regulations 2002";

(c) in paragraph 6(b), after "implantable" insert "relevant".

(4) In entry 72 (the substances listed in column 1 of the table in Appendix 12)(**10**), in the second column, in paragraph 4, after "of the Council" insert ", Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices as it has effect in EU law".

(5) In entry 74 (diisocyanates etc.), in the second column—

(a) for paragraph 6 substitute—

"**6.** The training:

(a) must comply with any other requirements contained in any other legislation that relate to the delivery of the training elements referred to in paragraph 5, and

(b) is in addition to any other training required by any other legislation.";

(b) in paragraph 7, omit the words from "in the official" to the end of the first sentence;

(c) in paragraph 9, in the opening text—

(i) for "Member States" substitute "The Agency",

(ii) for "their reports" substitute "its report",

(iii) for "117(1)" substitute "117(2)";

(d) in paragraph 9, omit subparagraphs (a) and (c);

(e) in paragraph 10, omit "Union".

(**9**) Entry 68 was amended by S.I. 2019/758.
(**10**) Entry 72 was amended by S.I. 2019/1144 as amended by S.I. 2020/1577.