STATUTORY INSTRUMENTS

2021 No. 904

CONSUMER PROTECTION
ENVIRONMENTAL PROTECTION
HEALTH AND SAFETY

The REACH etc. (Amendment) Regulations 2021

Sift requirements satisfied	*20th July 2021*
Made - - - -	*26th July 2021*
Laid before Parliament	*27th July 2021*
Coming into force - -	*30th September 2021*

The Secretary of State makes these Regulations in exercise of the powers conferred by section 8(1) of, and paragraph 21 of Schedule 7 to, the European Union (Withdrawal) Act 2018(**1**).

The requirements of paragraph 3(2) of Schedule 7 to that Act (relating to the appropriate Parliamentary procedure for these Regulations) have been satisfied.

PART 1

Introductory

Citation and commencement

1.—(1) These Regulations may be cited as the REACH etc. (Amendment) Regulations 2021.

(2) These Regulations come into force on 30th September 2021.

(**1**) 2018 c. 16. Section 8 was amended by section 27 of the European Union (Withdrawal Agreement) Act 2020 (c. 1).

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)(**2**) 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(**3**);

(b) Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices(**4**) 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(**5**) 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(**6**) (granting of authorisations), in paragraph 2, for the words from "medical device" to the end substitute "relevant medical device".

Article 62

5. In Article 62(**7**) (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".

(**2**) EUR 2006/1907.
(**3**) 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.
(**4**) 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).
(**5**) OJ No. L 117, 5.5.2017, p. 16, as last corrected by Corrigendum (OJ No. L 334, 27.12.2019, p. 167).
(**6**) Article 60(2) was amended by S.I. 2019/758.
(**7**) Article 62(6) was amended by S.I. 2019/758.

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(**8**)",

(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.)(**9**), in the second column, in paragraph 4(g)—

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

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

(3) In entry 68 (perfluorooctanoic acid)(**10**), 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",

(**8**) 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.
(**9**) Entry 51 was amended by S.I. 2019/1144 as amended by S.I. 2020/1577.
(**10**) Entry 68 was amended by S.I. 2019/758.

(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)(**11**), 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".

PART 3

Amendment of Implementing Regulations

Commission Implementing Regulation (EU) 2019/1692

9.—(1) Commission Implementing Regulation (EU) 2019/1692 on the application of certain registration and data-sharing provisions of Regulation (EC) No 1907/2006 after the expiry of the final registration deadline for phase-in substances(**12**) is amended in accordance with this regulation.

(2) In Article 3, after "Article 29 of Regulation 1907/2006" insert "as it has effect in EU law".

(3) Omit Article 4(1).

(4) In Article 4(2)—

(a) omit "pre-registrations made in accordance with Article 28 of Regulation (EC) No 1907/2006 shall no longer be valid and";

(b) after "and 27" insert "of Regulation (EC) No 1907/2006".

(5) Omit Article 5.

Commission Implementing Regulation (EU) 2020/1435

10.—(1) Commission Implementing Regulation (EU) 2020/1435 on the duties placed on registrants to update their registrations under Regulation (EC) No 1907/2006(**13**) is amended in accordance with this regulation.

(**11**) Entry 72 was amended by S.I. 2019/1144 as amended by S.I. 2020/1577.
(**12**) EUR 2019/1692.
(**13**) EUR 2020/1435.

(2) In Article 6(1), for "Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council" substitute "the GB mandatory classification and labelling list".

PART 4

Amendment of Implementing Decisions

Commission Implementing Decision C(2019) 5018

11.—(1) Commission Implementing Decision C(2019) 5018 granting an authorisation for certain uses of ammonium dichromate under REACH (BAE Systems (Operations) Limited and others)(**14**) is amended in accordance with this regulation.

(2) In Article 2(3), for "competent authority of the Member State" substitute "Agency (as defined in Article 2A of Regulation (EC) No 1907/2006)".

(3) In Article 2(9), for "competent authority of the Member State where the authorised use takes place" substitute "Agency".

(4) In Article 3(3), for "competent authority of the Member State" substitute "Agency".

(5) In Article 3(11), for "competent authority of the Member State where the authorised use takes place" substitute "Agency".

(6) In Article 6(5), for "competent authority of the Member State where the authorised use takes place" substitute "Agency".

(7) In Article 8—

(a) for "competent authority of the Member State where the authorised use takes place" substitute "Agency";

(b) omit "in an official language of that Member State".

Commission Implementing Decision C(2019) 5023

12.—(1) Commission Implementing Decision C(2019) 5023 granting an authorisation for certain uses of pentazinc chromate octahydroxide under REACH (Indestructible Paint Ltd.)(**15**) is amended in accordance with this regulation.

(2) In the first subparagraph of Article 2(2)(a), for "competent authority" substitute "Agency (as defined in Article 2A of Regulation (EC) No 1907/2006)".

(3) In Article 3(6), for "competent authority of the Member State where the use takes place" substitute "Agency".

(4) In Article 3(7), for "competent authority of the Member State where the authorised use takes place" substitute "Agency".

(5) In Article 3(10), for "competent authorities of the Member State where the use takes place" substitute "Agency".

(6) In Article 6, for the words from "competent authority of the Member State" to the end substitute "Agency".

(**14**) EUDN 2019/5018.
(**15**) EUDN 2019/5023.

Commission Implementing Decision C(2019) 7447

13.—(1) Commission Implementing Decision C(2019) 7447 partially granting an authorisation for certain uses of sodium chromate under REACH (Aviall Services Inc. and Wesco Aircraft EMEA Limited)(**16**) is amended in accordance with this regulation.

(2) In Article 2(3), for "competent authorities" substitute "Agency (as defined in Article 2A of Regulation (EC) No 1907/2006)".

(3) In Article 2(7), for "competent authorities of the Member States where an authorised use takes place" substitute "Agency".

(4) In the second subparagraph of Article 2(8), for "competent authorities of Member States" substitute "Agency".

(5) In Article 2(12), for "competent authorities of the Member State where the authorised uses take place" substitute "Agency".

(6) In Article 2(14), for "competent authorities of the Member State where the authorised uses take place" substitute "Agency".

(7) In Article 2(15), for "competent authority of the Member State where the use takes place" substitute "Agency".

(8) In Article 7—

(a) for "competent authority of the Member States where the authorised uses take place" substitute "Agency";

(b) for "competent authority of the Member State where the authorised use takes place in an official language of that Member State" substitute "Agency".

Commission Implementing Decision C(2019) 7448

14.—(1) Commission Implementing Decision C(2019) 7448 partially granting an authorisation for a use of chromium trioxide under REACH (Wesco Aircraft EMEA Limited)(**17**) is amended in accordance with this regulation.

(2) In Article 2(4), for "competent authority of the Member State where the authorised use takes place" substitute "Agency (as defined in Article 2A of Regulation (EC) No 1907/2006)".

(3) In Article 2(9), for "national competent authorities" substitute "the Agency".

(4) In Article 2(11), for "competent authorities of the Member State where the authorised uses take place" substitute "Agency".

(5) In Article 2(13), for "competent authority of the Member State where the authorised use takes place" substitute "Agency".

(6) In Article 2(14), for "competent authority of the Member State where the use takes place" substitute "Agency".

(7) In Article 6, for the words from "competent authority" to the end substitute "Agency".

Commission Implementing Decision C(2019) 7683

15.—(1) Commission Implementing Decision C(2019) 7683 partially granting an authorisation for a use of potassium dichromate under REACH (Wesco Aircraft EMEA Limited)(**18**) is amended in accordance with this regulation.

(**16**) EUDN 2019/7447.
(**17**) EUDN 2019/7448.
(**18**) EUDN 2019/7683.

(2) In Article 2(2), for "competent authorities" substitute "Agency (as defined in Article 2A of Regulation (EC) No 1907/2006)".

(3) In Article 2(4), for "competent authorities of the Member State where the authorised use takes place" substitute "Agency".

(4) In Article 2(8), for "national competent authorities" substitute "the Agency".

(5) In Article 2(11), for "competent authorities of the Member State where the authorised uses take place" substitute "Agency".

(6) In Article 2(13), for "competent authorities of the Member State where the authorised use takes place" substitute "Agency".

(7) In Article 2(14), for "competent authority of the Member State where the use takes place" substitute "Agency".

(8) In Article 6—

(a) for "competent authority of the Member State where the authorised use takes place" substitute "Agency";

(b) omit "in an official language of that Member State".

Commission Implementing Decision C(2020) 2056

16.—(1) Commission Implementing Decision C(2020) 2056 partially granting an authorisation for a use of dichromium tris(chromate) under REACH (Wesco Aircraft EMEA Limited)(**19**) is amended in accordance with this regulation.

(2) In Article 2(2), in the second subparagraph, for "competent authorities" substitute "Agency (as defined in Article 2A of Regulation (EC) No 1907/2006)".

(3) In Article 2(5), for the words from "competent authority" to the end substitute "Agency".

(4) In Article 2(6), in the second subparagraph, for the words from "competent authority" to the end substitute "Agency".

(5) In Article 2(12), for "competent authorities of the Member State where the use takes place" substitute "Agency".

(6) In Article 2(14), for the words from "competent authorities" to the end substitute "Agency".

(7) In Article 2(17), for "competent authority of the Member State where the use takes place" substitute "Agency".

(8) In Article 5(b), omit "Agency's".

(9) In Article 6, for the words from "competent authority" to the end substitute "Agency".

Commission Implementing Decision C(2020) 2073

17.—(1) Commission Implementing Decision C(2020) 2073 partially granting an authorisation for certain uses of potassium dichromate under REACH (Brenntag UK Ltd)(**20**) is amended in accordance with this regulation.

(2) In Article 2(2), in the second subparagraph, for "competent authorities of the Member State where the authorised use takes place" substitute "Agency (as defined in Article 2A of Regulation (EC) No 1907/2006)".

(3) In Article 2(5), for the words from "competent authority" to the end substitute "Agency".

(4) In Article 2(7), for the words from "competent authority" to the end substitute "Agency".

(**19**) EUDN 2020/2056.
(**20**) EUDN 2020/2073.

(5) In Article 2(14), for "competent authority of the Member State where the use takes place" substitute "Agency".

(6) In Article 7, for the words from "competent authority" to the end substitute "Agency".

Commission Implementing Decision C(2020) 2076

18.—(1) Commission Implementing Decision C(2020) 2076 partially granting an authorisation for certain uses of strontium chromate under REACH (Akzo Nobel Car Refinishes B.V. and others)(**21**) is amended in accordance with this regulation.

(2) In Article 2(2), in the third subparagraph, for "competent authorities" substitute "Agency (as defined in Article 2A of Regulation (EC) No 1907/2006)".

(3) In Article 2(5), for the words from "competent authorities" to the end substitute "Agency".

(4) In Article 2(6), in the second subparagraph, for the words from "competent authority" to the end substitute "Agency".

(5) In Article 2(9), for the words from "competent authorities" to the end substitute "Agency".

(6) In Article 2(12), for "competent authority of the Member State where the use takes place" substitute "Agency".

(7) In Article 7, for the words from "competent authority" to the end substitute "Agency".

Commission Implementing Decision C(2020) 2084

19.—(1) Commission Implementing Decision C(2020) 2084 partially granting an authorisation for certain uses of sodium dichromate under REACH (Brenntag UK Ltd and others)(**22**) is amended in accordance with this regulation.

(2) In Article 2(2), in the third subparagraph, for "competent authorities" substitute "Agency (as defined in Article 2A of Regulation (EC) No 1907/2006)".

(3) In Article 2(5), for the words from "competent authorities" to the end substitute "Agency".

(4) In Article 2(6), in the second subparagraph, for the words from "competent authority" to the end substitute "Agency".

(5) In Article 2(10), for the words from "competent authorities" to the end substitute "Agency".

(6) In Article 2(13), for "competent authority of the Member State where the use takes place" substitute "Agency".

(7) In Article 4(2), in the second subparagraph, for the words from "competent authority" to the end substitute "Agency".

(8) In Article 4(4), for "competent authority of the Member State where the authorised use takes place" substitute "Agency".

(9) In Article 6(3), for the words from "competent authorities" to the end substitute "Agency".

(10) In Article 6(6), for "competent authority of the Member State where the use takes place" substitute "Agency".

(11) In Article 8, for the words from "competent authority" to the end substitute "Agency".

(**21**) EUDN 2020/2076.
(**22**) EUDN 2020/2084.

Commission Implementing Decision C(2020) 2089

20.—(1) Commission Implementing Decision C(2020) 2089 partially granting an authorisation for certain uses of potassium hydroxyoctaoxodizincatedichromate under REACH (PPG Industries UK Ltd. and others)(**23**) is amended in accordance with this regulation.

(2) In Article 2(2), in the third subparagraph, for the words from "competent authorities" to the end substitute "Agency (as defined in Article 2A of Regulation (EC) No 1907/2006)".

(3) In Article 2(5), for the words from "competent authorities" to the end substitute "Agency".

(4) In Article 2(6), in the second subparagraph, for the words from "competent authorities" to the end substitute "Agency".

(5) In Article 2(10), for the words from "competent authorities" to the end substitute "Agency".

(6) In Article 2(13), for "competent authority of the Member State where the uses take place" substitute "Agency".

(7) In Article 7, for the words from "competent authority" to the end substitute "Agency".

Commission Implementing Decision C(2020) 6231

21.—(1) Commission Implementing Decision C(2020) 6231 partially granting an authorisation for a use of strontium chromate under REACH (Wesco Aircraft EMEA Limited and others)(**24**) is amended in accordance with this regulation.

(2) In Article 2(2), in the second subparagraph, for "competent authorities" substitute "Agency".

(3) In Article 2(5), for the words from "competent authority" to the end substitute "Agency".

(4) In Article 2(6), for "competent authority of the Member States" substitute "Agency".

(5) In Article 2(10), for "competent authorities of the Member States where the use takes place" substitute "Agency".

(6) In Article 2(12), for the words from "competent authorities" to the end substitute "Agency".

(7) In Article 2(15), for "competent authority of the Member State where the use takes place" substitute "Agency".

(8) In Article 5(b), omit "Agency's".

(9) In Article 6, for the words from "competent authority" to the end substitute "Agency".

Commission Implementing Decision C(2020) 6518

22.—(1) Commission Implementing Decision C(2020) 6518 partially granting an authorisation for a use of sodium dichromate under REACH (Wesco Aircraft EMEA Limited)(**25**) is amended in accordance with this regulation.

(2) In Article 2(2), in the second subparagraph, for "competent authorities" substitute "Agency (as defined in Article 2A of Regulation (EC) No 1907/2006)".

(3) In Article 2(5), for the words from "competent authority" to the end substitute "Agency".

(4) In Article 2(12), for the words from "competent authorities" to the end substitute "Agency".

(5) In Article 2(15), for "competent authority of the Member State where the use takes place" substitute "Agency".

(6) In Article 6, for the words from "competent authority" to the end substitute "Agency".

(**23**) EUDN 2020/2089.
(**24**) EUDN 2020/6231.
(**25**) EUDN 2020/6518.

Commission Implementing Decision C(2020) 8797

23.—(1) Commission Implementing Decision C(2020) 8797 partially granting an authorisation for certain uses of chromium trioxide under REACH (Chemservice GmbH and others)(**26**) is amended in accordance with this regulation.

(2) In Article 2(2), in the second subparagraph, for "competent authorities of the Member State where an authorised use takes place" substitute "Agency (as defined in Article 2A of Regulation (EC) No 1907/2006)".

(3) In Article 2(5), for "competent authorities of the Member States where the authorised uses take place" substitute "Agency".

(4) In Article 2(7), for the words from "competent authorities" to the end substitute "Agency".

(5) In Article 6(2), for the words from "competent authorities" to the end substitute "Agency".

(6) In Article 8(5), for the words from "competent authorities" to the end substitute "Agency".

(7) In Article 10, for the words from "competent authority" to the end substitute "Agency".

Rebecca Pow
Parliamentary Under Secretary of State
Department for Environment, Food and Rural Affairs

26th July 2021

(**26**) EUDN 2020/8797.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations are made in exercise of the powers conferred by section 8(1) of the European Union (Withdrawal) Act 2018 (c. 16) in order to address failures of retained EU law to operate effectively and other deficiencies (in particular under section 8(2)(a) to (d) and (g)) arising from the withdrawal of the United Kingdom from the European Union.

Part 2 of these Regulations amends the retained version of Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

Part 3 of these Regulations amends the retained versions of two Commission Implementing Regulations made under Regulation (EC) No 1907/2006. Regulation 9 amends Regulation (EU) 2019/1692 relating to the application of certain registration and data-sharing provisions. Regulation 10 amends Regulation (EU) 2020/1435 relating to registrants' duties to update their registrations.

Part 4 of these Regulations amends a number of Commission Implementing Decisions that granted authorisations under Regulation (EC) No 1907/2006 before the end of the transition period.

An impact assessment has not been produced for this instrument as no, or no significant, impact on the private, voluntary or public sector is foreseen.