

---

STATUTORY INSTRUMENTS

---

**2019 No. 1144**

**EXITING THE EUROPEAN UNION  
CONSUMER PROTECTION  
ENVIRONMENTAL PROTECTION  
HEALTH AND SAFETY**

**The REACH etc. (Amendment etc.)  
(EU Exit) (No. 3) Regulations 2019**

<i>Sift requirements satisfied</i>	<i>2nd July 2019</i>
	<i>10.00 a.m. on 18th</i>
<i>Made - - - -</i>	<i>July 2019</i>
	<i>16.30 p.m. on 18th</i>
<i>Laid before Parliament</i>	<i>July 2019</i>
<i>Coming into force in accordance with regulation 1</i>	

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<sup>(1)</sup>.

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

**Citation and commencement**

1. These Regulations may be cited as the REACH etc. (Amendment etc.) (EU Exit) (No. 3) Regulations 2019 and come into force immediately before exit day.

**Amendment of the REACH etc. (Amendment etc.) (EU Exit) Regulations 2019**

2. The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019<sup>(2)</sup> are amended as follows.

**Amendment of Schedule 1**

3.—(1) Schedule 1 (amendment of Titles 1 to 15) is amended in accordance with this regulation.

(2) In sub-paragraph (3)(a)(ii) of paragraph 34—

---

(1) 2018 c. 16.

(2) S.I. 2019/758, amended by S.I. 2019/858.

- (a) for “by 31 May 2020” substitute “within 12 months of exit day”;
- (b) for “each year after 2020” substitute “in each subsequent year”.
- (3) For sub-paragraph (4)(b) of paragraph 45 substitute—
  - “(b) in the second subparagraph, in the second sentence, for “by 1 June 2009” substitute “within 12 months of exit day”.”.
- (4) In sub-paragraph (3)(c) of paragraph 47, for ““the Medical Devices” substitute ““Parts II to IV of the Medical Devices””.
- (5) In sub-paragraph (3) of paragraph 49, for ““the Medical Devices” substitute ““Parts II to IV of the Medical Devices””.
- (6) In paragraph 95—
  - (a) for sub-paragraph (3)(a) substitute—
    - “(a) in the first sentence, for “By 1 June 2019” substitute “Within 18 months of exit day”.”;
  - (b) for sub-paragraph (6)(a) substitute—
    - “(a) in the first sentence, for “By 1 June 2019” substitute “Within 18 months of exit day”.”;
  - (c) for sub-paragraph (7)(a) substitute—
    - “(a) for “by 1 June 2019” substitute “within 18 months of exit day”.”.

## **Amendment of Schedule 2**

- 4.—(1) Schedule 2 (transitional provision) is amended in accordance with this regulation.
- (2) In inserted Article 127A—
  - (a) in paragraph 3(a), for “during the 2 year period” substitute “in the period beginning with 29 March 2017 and ending immediately”;
  - (b) in the second sub-paragraph of paragraph 6, for “during the 2 year period before exit” substitute “in the period beginning with 29 March 2017 and ending immediately before exit day”.
- (3) After inserted Article 127G insert—  
“Article 127GA

### *Substances of very high concern: sunset dates and latest application dates*

- 1. Paragraphs 2 and 3 apply where—
  - (a) immediately before exit day, a substance is included in Annex 14 to EU REACH;
  - (b) the EU latest application date fell before or during the relevant pre-exit period;
  - (c) the EU sunset date fell during the relevant pre-exit period;
  - (d) before the EU latest application date, an application had been made for the grant of an authorisation in accordance with Articles 60 to 64 of EU REACH in relation to the substance (the “authorisation application”); and
  - (e) immediately before exit day, the authorisation application was still under consideration (see paragraph 11).
- 2. Where, immediately before exit day, a person established in the United Kingdom may place the substance on the market or use it himself in reliance on Article 56(1)(d) of EU

REACH by virtue of the authorisation application having been made, this Regulation has effect subject to the modifications set out in paragraph 3.

**3.** As respects that person placing the substance on the market or using it himself on and after exit day—

- (a) the UK latest application date, and
- (b) the UK sunset date,

both fall on the transitional cut-off date (rather than on the dates specified in Annex 14 for that substance).

**4.** Paragraphs 5 and 6 apply where—

- (a) immediately before exit day, a substance is included in Annex 14 to EU REACH;
- (b) the EU latest application date fell during the relevant pre-exit period;
- (c) the EU sunset date falls after the end of that period;
- (d) before the EU latest application date, an application had been made for the grant of an authorisation in accordance with Articles 60 to 64 of EU REACH in relation to the substance (the “authorisation application”); and
- (e) immediately before exit day, the authorisation application was still under consideration (see paragraph 11).

**5.** Where, on and after the UK sunset date, a person established in the United Kingdom would be able to place the substance on the market or use it himself in reliance on Article 56(1) (d) of this Regulation had the authorisation application been made under this Regulation, this Regulation has effect subject to the modifications set out in paragraph 6.

**6.** As respects that person placing the substance on the market or using it himself on and after exit day—

- (a) the UK latest application date, and
- (b) the UK sunset date,

both fall on the transitional cut-off date (rather than on the dates specified in Annex 14 for that substance).

The effect of this paragraph is to be ignored in reading the reference to the UK sunset date in paragraph 5.

**7.** Paragraph 8 applies where—

- (a) immediately before exit day, a substance is included in Annex 14 to EU REACH; and
- (b) the UK latest application date falls during the 18 month post-exit period.

**8.** As respects a person established in the United Kingdom placing the substance on the market or using it himself on and after exit day, the UK latest application date falls on the transitional cut-off date (rather than on the date specified in Annex 14 for that substance).

**9.** Where paragraph 3, 6 or 8 modifies this Regulation, Article 56(1) has effect with the following provision substituted for point (d)—

- “(d) the UK sunset date (within the meaning of Article 127GA) has been reached and he made an application before the UK latest application date (within the meaning of Article 127GA) but a decision on the application for authorisation has not yet been taken; or”.

**10.** Where paragraph 3 or 6 modifies the date that is the UK sunset date, any reference in this Regulation to the date of the kind referred to in Article 58(1)(c)(i) has effect subject to the modification made by paragraph 3 or 6.

**11.** For the purposes of paragraph 1(e) or 4(e), the authorisation application is “still under consideration” unless—

- (a) the Commission has made a final decision granting or refusing the authorisation application, or
- (b) the authorisation application—
  - (i) has the relevant connection with the United Kingdom (within the meaning of Article 127G), and
  - (ii) is at the final decision stage (within the meaning of Article 127G).

**12.** In this Article—

“EU latest application date”, in relation to a substance, means the date of the kind referred to in Article 58(1)(c)(ii) of EU REACH that is specified in Annex 14 to EU REACH in relation to the substance;

“EU sunset date”, in relation to a substance, means the date of the kind referred to in Article 58(1)(c)(i) of EU REACH that is specified in Annex 14 to EU REACH in relation to the substance;

“relevant pre-exit period” means the period that—

- (a) begins with 29 March 2017, and
- (b) ends immediately before exit day;

“transitional cut-off date” means the last day of the 18 month post-exit period;

“UK latest application date”, in relation to a substance, means the date of the kind referred to in Article 58(1)(c)(ii) of this Regulation that is specified in Annex 14 to this Regulation in relation to the substance;

“UK sunset date”, in relation to a substance, means the date of the kind referred to in Article 58(1)(c)(i) of this Regulation that is specified in Annex 14 to this Regulation in relation to the substance;

“18 month post-exit period” means the period of 18 months beginning with the day after that on which exit day falls.”.

(4) In inserted Article 127N—

- (a) in paragraph 3(a), for “during the 2 year period” substitute “in the period beginning with 29 March 2017 and ending immediately”;
- (b) in the second subparagraph of paragraph 5, for “during the 2 year period” substitute “in the period beginning with 29 March 2017 and ending immediately”.

### **Amendment of Schedule 3**

**5.—(1)** Schedule 3 (amendment of the Annexes and Appendices to the REACH Regulation) is amended in accordance with this regulation.

(2) After paragraph 28, insert—

**“28A.—(1)** In entry 51 of the table (Bis(2-ethylhexyl) phthalate (DEHP) etc.), the second column is amended as follows.

- (2) In paragraph 4(c), for “[Directive 2007/46/EC](#)” substitute “the Road Vehicles (Approval) Regulations 2009(3)”.
- (3) In paragraph 4(g), for “[Directives 90/385/EEC, 93/42/EEC or 98/79/EC](#)” substitute “Parts II to IV of the Medical Devices Regulations 2002(4)”.
- (4) In paragraph 4(h), for “[Directive 2011/65/EU](#)” substitute “the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012(5)”.
- (5) In paragraph 4(i), for the words from “[Regulation \(EC\) No 726/2004](#)” to the end substitute “the Veterinary Medicines Regulations 2013(6) or the Human Medicines Regulations 2012(7)”.
- (6) In paragraph 6(a), for “[Regulation \(EC\) No 216/2008](#)” substitute “[Regulation \(EU\) 2018/1139](#)”.
- (3) In paragraph 37, for “the Medical Devices” substitute “Part II of the Medical Devices”.
- (4) After paragraph 37, insert—
- “**37A.**—(1) In entry 72 of the table (the substances listed in column 1 of the table in Appendix 12), the second column is amended as follows.
- (2) In paragraph 4, for “[Regulation \(EU\) 2017/745](#)” to the end substitute “Part VIII of the Medical Devices Regulations 2002(8)”.
- (3) In paragraph 6, omit “Union”.
- (4) In paragraph 7—
- (a) for “Commission” substitute “Secretary of State”;
- (b) omit “and, if appropriate, modify that point accordingly”.
- (5) After paragraph 39, insert—
- “**40.**—(1) Appendix 12 (entry 72 – restricted substances and maximum concentration limits by weight in homogenous materials) is amended as follows.
- (2) For “Part 3 of Annex VI to [Regulation \(EC\) No 1272/2008](#)” wherever it occurs, substitute “the UK mandatory classification and labelling list”.
- ”

*Thérèse Coffey*  
Parliamentary Under Secretary of State  
Department for Environment, Food and Rural  
Affairs

10.00 a.m. on 18th July 2019

---

(3) S.I. 2009/717, amended by S.I. 2011/1043, 1946, 2013/602, 2018/235, 236, 673, 984.

(4) 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.

(5) S.I. 2012/3032, amended by S.I. 2014/1771, 2018/942.

(6) S.I. 2013/2033, amended by S.I. 2014/599, 2018/761.

(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.

(8) S.I. 2002/618, amended by S.I. 2019/791; there are other amending instruments but none is relevant.

**Status:** This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

---

## EXPLANATORY NOTE

*(This note is not part of the Regulations)*

These Regulations are made in exercise of the powers conferred by 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 (“UK”) from the European Union.

These Regulations amend the REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758) (the “Exit Regulations”). The Exit Regulations amend Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency (“Regulation (EC) No 1907/2006”).

Regulation 3(2), (3) and (6) amends deadlines that operate by reference to a fixed date so that they are, instead, relative to exit day. Regulations 3(4), (5) and 5(3) amend cross-references to the Medical Devices Regulations 2002 (S.I. 2002/618) to specify which Part of those Regulations are referred to in each case.

Regulation 4(2) and (4) amend the criteria in the transitional provisions for a registration to have a relevant past connection with the UK. Regulation 4(3) inserts a new transitional provision that extends the last application and sunset dates for certain substances in relation to certain users. The last application date for a substance must fall before, or within 18 months of, exit day for this provision to apply.

Regulation 5(2), (4) and (5) corrects deficiencies in amendments made to Regulation (EC) No 1907/2006 by Commission Regulation (EU) 2018/1513 and Commission Regulation (EU) 2018/2005.

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.