

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (Text with EEA relevance)

## [<sup>X1</sup>TITLE I

### GENERAL ISSUES

#### [<sup>X1</sup> CHAPTER 1

#### **Aim, scope and application**

##### *Article 1*

#### **Aim and scope**

1 The purpose of this Regulation is to ensure a high level of protection of human health and the environment, including the promotion of alternative methods for assessment of hazards of substances, as well as the free circulation of substances <sup>F1</sup>... while enhancing competitiveness and innovation.

2 This Regulation lays down provisions on substances and [<sup>F2</sup>mixtures] within the meaning of Article 3. These provisions shall apply to the manufacture, placing on the market or use of such substances on their own, in [<sup>F2</sup>mixtures] or in articles and to the placing on the market of [<sup>F2</sup>mixtures].

3 This Regulation is based on the principle that it is for manufacturers, importers and downstream users to ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment. Its provisions are underpinned by the precautionary principle.

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#### **Textual Amendments**

- F1** Words in [Art. 1\(1\)](#) omitted (31.12.2020) by virtue of [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), [reg. 1\(1\)](#), [Sch. 1 para. 1](#); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F2** Substituted by [Regulation \(EC\) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation \(EC\) No 1907/2006 \(Text with EEA relevance\)](#).

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*Changes to legislation:* There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council, CHAPTER 1. (See end of Document for details)

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## Article 2

### Application

- 1 This Regulation shall not apply to:
- a radioactive substances within the scope of [F3]retained EU law that transposed Council Directive 2013/59/Euratom laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation];
  - b substances, on their own, in a [F2]mixture] or in an article, which are subject to customs supervision, provided that they do not undergo any treatment or processing, and which are in temporary storage, or in a free zone or free warehouse with a view to re-exportation, or in transit;
  - c non-isolated intermediates;
  - d the carriage of dangerous substances and dangerous substances in dangerous [F2]mixtures] by rail, road, inland waterway, sea or air.
- 2 Waste as defined in [F4]Article 3(1) of Directive 2008/98/EC] of the European Parliament and of the Council <sup>(1)</sup> is not a substance, [F2]mixture] or article within the meaning of Article 3 of this Regulation.
- [F5]2A For the purposes of this Regulation, “Directive 2008/98/EC” means that Directive as last amended by Directive (EU) 2018/851, and read in accordance with paragraphs 2B and 2C.
- 2B Article 5 is to be read as if—
- a in paragraph 1, “Member States shall take appropriate measures to ensure that” were omitted;
  - b after paragraph 1 there were inserted—
    - 1A a in accordance with any regulations setting out detailed criteria on the application of the conditions in paragraph 1 to specific substances or objects; and
    - b having regard to any guidance published by the appropriate authority or the appropriate agency for the purposes of this Article.;
  - c paragraphs 2 and 3 were omitted.
- 2C Article 6 is to be read as if—
- a in paragraph 1, “Member States shall take appropriate measures to ensure that” were omitted;
  - b after paragraph 1 there were inserted—
    - 1A a in accordance with any regulations or retained direct EU legislation setting out detailed criteria on the application of the conditions in paragraph 1 to specific types of waste; and
    - b having regard to any guidance published by the appropriate authority or the appropriate agency for the purposes of this Article.;
  - c in paragraph 2—
    - i the first subparagraph were omitted;
    - ii in the second subparagraph, for “Those detailed criteria” there were substituted “Any detailed criteria set out in guidance as referred to in paragraph 1A”;
    - iii the third and fourth subparagraphs were omitted;
  - d paragraph 3 were omitted;

- e in paragraph 4—
- i in the first subparagraph—
    - aa in the first sentence, for the words from the beginning to “Member State”, there were substituted “Where criteria have not been set out as referred to in paragraph 1A(a), the appropriate agency”;
    - bb the second sentence were omitted;
  - ii in the second subparagraph—
    - aa for “Member States” there were substituted “The appropriate agency”;
    - bb “by competent authorities” were omitted.
- 2D In paragraphs 2B and 2C, “appropriate agency” means—
- a the Environment Agency, in relation to England;
  - b the Natural Resources Body for Wales, in relation to Wales;
  - c the Scottish Environment Protection Agency, in relation to Scotland.]
- 3 [F<sup>6</sup>The Secretary of State] may allow for exemptions from this Regulation in specific cases for certain substances, on their own, in a [F<sup>2</sup>mixture] or in an article, where necessary in the interests of defence.
- F<sup>7</sup> 4 .....
- 5 The provisions of Titles II, V, VI and VII shall not apply to the extent that a substance is used:
- [F<sup>8</sup>a in medicinal products for human or veterinary use within the scope of the Veterinary Medicines Regulations 2013, or the Human Medicines Regulations 2012;]
  - b in food or feedingstuffs in accordance with Regulation (EC) No 178/2002 including use:
    - (i) [F<sup>9</sup>as a food additive in foodstuffs as defined by Article 3(2)(a) of Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives;]
    - (ii) [F<sup>10</sup>as a flavouring in foodstuffs within the scope of Regulation (EC) No 1334/2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods or Commission Implementing Regulation (EU) No 872/2012 adopting the list of flavouring substances provided for by Regulation (EC) No 2232/96 of the European Parliament and of the Council, introducing it in Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council;]
    - (iii) as an additive in feedingstuffs within the scope of Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition <sup>(2)</sup>;
    - (iv) [F<sup>11</sup>in animal nutrition within the scope of Article 2(1) of Regulation (EC) No 767/2009.]
- 6 The provisions of Title IV shall not apply to the following [F<sup>2</sup>mixtures] in the finished state, intended for the final user:
- [F<sup>12</sup>a medicinal products for human or veterinary use within the scope of the Veterinary Medicines Regulations 2013, or the Human Medicines Regulations 2012;]
  - [F<sup>13</sup>b cosmetic products as defined in Regulation (EC) No 1223/2009 on cosmetic products;]
  - [F<sup>14</sup>c medical devices which are invasive or used in direct physical contact with the human body in so far as legislation relating to the classification and labelling of dangerous

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- substances and mixtures applies to them which ensures the same level of information provision and protection as Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures;]
- d food or feedingstuffs in accordance with Regulation (EC) No 178/2002 including use:
- (i) [<sup>F15</sup>as a food additive in foodstuffs as defined by Article 3(2)(a) of Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives;]
  - (ii) [<sup>F15</sup>as a flavouring in foodstuffs within the scope of Regulation (EC) No 1334/2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods or Commission Implementing Regulation (EU) No 872/2012 adopting the list of flavouring substances provided for by Regulation (EC) No 2232/96 of the European Parliament and of the Council, introducing it in Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council;]
  - (iii) as an additive in feedingstuffs within the scope of Regulation (EC) No 1831/2003;
  - (iv) [<sup>F16</sup>in animal nutrition within the scope of Article 2(1) of Regulation (EC) No 767/2009.]
- 7 The following shall be exempted from Titles II, V and VI:
- a substances included in Annex IV, as sufficient information is known about these substances that they are considered to cause minimum risk because of their intrinsic properties;
  - b substances covered by Annex V, as registration is deemed inappropriate or unnecessary for these substances and their exemption from these Titles does not prejudice the objectives of this Regulation;
  - c substances on their own or in [<sup>F2</sup>mixtures], registered in accordance with Title II, exported [<sup>F17</sup>from Great Britain] by an actor in the supply chain and re-imported [<sup>F18</sup>into Great Britain] by the same or another actor in the same supply chain who shows that:
    - (i) the substance being re-imported is the same as the exported substance;
    - (ii) he has been provided with the information in accordance with Articles 31 or 32 relating to the exported substance;
  - d substances, on their own, in [<sup>F2</sup>mixtures] or in articles, which have been registered in accordance with Title II and which are recovered in [<sup>F19</sup>Great Britain] if:
    - (i) the substance that results from the recovery process is the same as the substance that has been registered in accordance with Title II; and
    - (ii) the information required by Articles 31 or 32 relating to the substance that has been registered in accordance with Title II is available to the establishment undertaking the recovery.
- 8 On-site isolated intermediates and transported isolated intermediates shall be exempted from:
- a Chapter 1 of Title II, with the exception of Articles 8 and 9; and
  - b Title VII.
- 9 The provisions of Titles II and VI shall not apply to polymers. ]

**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council, CHAPTER 1. (See end of Document for details)

### Textual Amendments

- F2** Substituted by Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (Text with EEA relevance).
- F3** Words in Art. 2(1)(a) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 2(2)**; 2020 c. 1, Sch. 5 para. 1(1)
- F4** Words in Art. 2(2) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 2(3)**; 2020 c. 1, Sch. 5 para. 1(1)
- F5** Art. 2(2A)-(2D) inserted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 2(4)** (as amended by S.I. 2020/1577, regs. 1(1)(b), **4(2)**); 2020 c. 1, Sch. 5 para. 1(1)
- F6** Words in Art. 2(3) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 2(5)**; 2020 c. 1, Sch. 5 para. 1(1)
- F7** Art. 2(4) omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 2(6)**; 2020 c. 1, Sch. 5 para. 1(1)
- F8** Art. 2(5)(a) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 2(7)(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F9** Art. 2(5)(b)(i) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 2(7)(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F10** Art. 2(5)(b)(ii) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 2(7)(c)**; 2020 c. 1, Sch. 5 para. 1(1)
- F11** Art. 2(5)(b)(iv) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 2(7)(d)**; 2020 c. 1, Sch. 5 para. 1(1)
- F12** Art. 2(6)(a) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 2(8)(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F13** Art. 2(6)(b) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 2(8)(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F14** Art. 2(6)(c) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 2(8)(c)**; 2020 c. 1, Sch. 5 para. 1(1)
- F15** Art. 2(6)(d)(i)(ii) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 2(8)(d)**; 2020 c. 1, Sch. 5 para. 1(1)
- F16** Art. 2(6)(d)(iv) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 2(8)(e)**; 2020 c. 1, Sch. 5 para. 1(1)
- F17** Words in Art. 2(7)(c) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 2(9)(a)** (as amended by S.I. 2020/1577, regs. 1(1)(b), **4(3)**); 2020 c. 1, Sch. 5 para. 1(1)
- F18** Words in Art. 2(7)(c) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 2(9)(b)** (as amended by S.I. 2020/1577, regs. 1(1)(b), **4(3)**); 2020 c. 1, Sch. 5 para. 1(1)
- F19** Words in Art. 2(7)(d) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 2(10)** (as amended by S.I. 2020/1577, regs. 1(1)(b), **4(4)(a)(b)**); 2020 c. 1, Sch. 5 para. 1(1)

### Editorial Information

- X1** Substituted by Corrigendum to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as

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well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (Official Journal of the European Union L 396 of 30 December 2006).

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- (1) [<sup>XI</sup>OJ L 114, 27.4.2006, p. 9.]
- (2) [<sup>XI</sup>OJ L 268, 18.10.2003, p. 29. Regulation as amended by Commission Regulation (EC) No 378/2005 (OJ L 59, 5.3.2005, p. 8).]

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