

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)

[^{X1}TITLE I

GENERAL ISSUES

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 ^{F1}... while enhancing competitiveness and innovation.

2 This Regulation lays down provisions on substances and [^{F2}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 [^{F2}mixtures] or in articles and to the placing on the market of [^{F2}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.

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 \(Text with EEA relevance\)](#).

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, TITLE I. (See end of Document for details)

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 ⁽¹⁾ 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 [F⁶The Secretary of State] may allow for exemptions from this Regulation in specific cases for certain substances, on their own, in a [F²mixture] or in an article, where necessary in the interests of defence.
- F⁷ 4
- 5 The provisions of Titles II, V, VI and VII shall not apply to the extent that a substance is used:
- [F⁸a 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) [F⁹as 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) [F¹⁰as 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 ⁽²⁾;
 - (iv) [F¹¹in 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 [F²mixtures] in the finished state, intended for the final user:
- [F¹²a medicinal products for human or veterinary use within the scope of the Veterinary Medicines Regulations 2013, or the Human Medicines Regulations 2012;]
 - [F¹³b cosmetic products as defined in Regulation (EC) No 1223/2009 on cosmetic products;]
 - [F¹⁴c 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

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, TITLE I. (See end of Document for details)

- 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) [F15as 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) [F15as 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) [F16;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 [F2mixtures], registered in accordance with Title II, exported [F17from Great Britain] by an actor in the supply chain and re-imported [F18into 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 [F2mixtures] or in articles, which have been registered in accordance with Title II and which are recovered in [F19Great 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, TITLE I. (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)

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, TITLE 1. (See end of Document for details)

CHAPTER 2

Definitions and general provision

f²⁰ Article 2A

The Agency

1 The functions and powers of the Agency under the REACH legislation are to be functions and powers of the HSE.

Accordingly, any reference to the Agency in the REACH legislation must be read as meaning the HSE.

2 The general incidental powers of the HSE are to be exercisable for the purpose of carrying out the functions of the Agency under the REACH legislation.

But that does not limit the powers which the HSE has under the REACH legislation.

3 The non-REACH functions of the HSE are not limited by the functions of the Agency under the REACH legislation.

Accordingly, the HSE is not prevented from carrying out non-REACH functions in relation to a matter just because any of the functions of the Agency under the REACH legislation is also exercisable, or has been exercised, in relation to that matter.

4 The power of the Secretary of State under section 12(2)(a) of HASWA 1974 to give directions (as read with section 12(4) of HASWA 1974) is to be exercisable with respect to the functions of the Agency under the REACH legislation.

The Secretary of State may not give any such directions with regard to the enforcement of the REACH legislation in any particular case.

The Secretary of State must consider any request made by any of the other appropriate authorities for the Secretary of State to give a direction by virtue of this paragraph.

The function of giving directions by virtue of this section is subject to the consent requirement in Article 4A (whether or not there has been a request under the previous subparagraph).

5 In this Article—

“general incidental powers” means the powers which the HSE has under—

a section 13 of HASWA 1974, and

b Schedule 2 to HASWA 1974;

“HASWA 1974” means the Health and Safety at Work etc. Act 1974;

“HSE” means the Health and Safety Executive;

“non-REACH function” means any function which arises otherwise than under the REACH legislation;

“REACH legislation” means—

a this Regulation,

b any instrument made under this Regulation, and

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- c any retained direct EU legislation that was originally made under EU REACH.

Textual Amendments

F20 Arts. 2A, 2B inserted (31.12.2020) by [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/758), reg. 1(1), [Sch. 1 para. 3](#) (as amended by S.I. 2020/1577, regs. 1(1)(b), [4\(5\)](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

Article 2B

Advice from Environment Agency or other environmental regulators to Agency

- 1 The Agency must comply with paragraph 2 when exercising—
- a its functions under—
- i Article 7(5),
 - ii Article 9(4), (7) and (8),
 - iii Article 21,
 - iv Articles 40(1) and (3), 41(1), (3) and (5), 42(1), 43, 44, 45, 46(1) and (3), 48, 49, 51 and 52,
 - v Articles 58(3) and (4) and 59(1), (2), (3), (6) and (7),
 - vi Article 64(1), (3), (4), (5) and (6),
 - vii Articles 69, 70 and 71, and
- b any of its other functions under this Regulation,
- if, and to the extent that, the exercise of the function involves consideration of any relevant environmental issues.
- 2 The Agency must—
- a obtain the advice of the Environment Agency before exercising the function concerned, and
- b use the advice obtained when exercising the function concerned.
- 3 Whenever the advice of the Environment Agency is sought by the Agency under this Article, the Environment Agency must collaborate with the other environmental regulators when formulating the advice.
- 4 If, as part of a collaboration under paragraph 3, one of the other environmental regulators gives advice to the Environment Agency, the Environment Agency must pass that advice on to the Agency if that other environmental regulator requires it to do so.
- 5 In this Article—
- “other environmental regulator” means—
- a in relation to Wales, the Natural Resources Body for Wales;
 - b in relation to Scotland, the Scottish Environment Protection Agency;
- “relevant environmental issue” means—
- a exposure of the environment to chemicals;
 - b exposure of humans to chemicals in the environment;

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- c assessment of the potential effect of chemicals on the environment;
- d measures aimed at controlling the release of chemicals into the environment.]

Textual Amendments

F20 Arts. 2A, 2B inserted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 3** (as amended by S.I. 2020/1577, regs. 1(1)(b), **4(5)**); 2020 c. 1, **Sch. 5 para. 1(1)**

Article 3

Definitions

For the purposes of this Regulation:

- A1. [^{F21}EU REACH: means Regulation (EC) No 1907/2006 of the European Parliament and of the Council as it has effect in EU law;]
- A2. [^{F21}appropriate authority: means—
 - a the Secretary of State, in relation to England;
 - b the Scottish Ministers, in relation to Scotland;
 - c the Welsh Ministers, in relation to Wales;]
- 1. substance: means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition;
- 2. [^{F2}mixture]: means a mixture or solution composed of two or more substances;
- 3. article: means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition;
- 4. producer of an article: means any natural or legal person who makes or assembles an article within [^{F22}Great Britain];
- 5. polymer: means a substance consisting of molecules characterised by the sequence of one or more types of monomer units. Such molecules must be distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units. A polymer comprises the following:
 - (a) a simple weight majority of molecules containing at least three monomer units which are covalently bound to at least one other monomer unit or other reactant;
 - (b) less than a simple weight majority of molecules of the same molecular weight.

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In the context of this definition a ‘ monomer unit ’ means the reacted form of a monomer substance in a polymer;

6. monomer: means a substance which is capable of forming covalent bonds with a sequence of additional like or unlike molecules under the conditions of the relevant polymer-forming reaction used for the particular process;
7. registrant: means the manufacturer or the importer of a substance or the producer or importer of an article submitting a registration for a substance;
8. manufacturing: means production or extraction of substances in the natural state;
9. manufacturer: means any natural or legal person established within [F²³Great Britain] who manufactures a substance within [F²³Great Britain];
10. import: means the physical introduction into [F²⁴Great Britain];
- 10A. [F²⁵protected NI import: has the meaning given by Article 139A(2);]
- 10B. [F²⁵qualifying Northern Ireland good: has the meaning given to it from time to time in regulations made under section 8C(6) of the European Union (Withdrawal) Act 2018;]
11. importer: means any natural or legal person established within [F²⁶Great Britain] who is responsible for import;
12. placing on the market: means supplying or making available, whether in return for payment or free of charge, to a third party. Import shall be deemed to be placing on the market;
13. downstream user: means any natural or legal person established within [F²⁷Great Britain], other than the manufacturer or the importer, who uses a substance, either on its own or in a [F²mixture], in the course of his industrial or professional activities. A distributor or a consumer is not a downstream user. A re-importer exempted pursuant to Article 2(7)(c) shall be regarded as a downstream user;
14. distributor: means any natural or legal person established within [F²⁸Great Britain], including a retailer, who only stores and places on the market a substance, on its own or in a [F²mixture], for third parties;
15. intermediate: means a substance that is manufactured for and consumed in or used for chemical processing in order to be transformed into another substance (hereinafter referred to as synthesis):
 - (a) non-isolated intermediate: means an intermediate that during synthesis is not intentionally removed (except for sampling) from the equipment in which the synthesis takes place. Such equipment includes the reaction vessel, its ancillary equipment, and any equipment through which the substance(s) pass(es) during a continuous flow or batch process as well as the pipework for transfer from one vessel to another for the purpose of the next reaction step, but it excludes tanks or other vessels in which the substance(s) are stored after the manufacture;
 - (b) on-site isolated intermediate: means an intermediate not meeting the criteria of a non-isolated intermediate and where the manufacture of the intermediate and the synthesis of (an)other substance(s) from that intermediate take place on the same site, operated by one or more legal entities;

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- (c) transported isolated intermediate: means an intermediate not meeting the criteria of a non-isolated intermediate and transported between or supplied to other sites;
16. site: means a single location, in which, if there is more than one manufacturer of (a) substance(s), certain infrastructure and facilities are shared;
17. actors in the supply chain: means all manufacturers and/or importers and/or downstream users in a supply chain;
18. [^{F29}Agency: see Article 2A;]
- 18A. [^{F29}ECHA: means the European Chemicals Agency established under EU REACH;]
19. ^{F30}
20. phase-in substance: means a substance which meets at least one of the following criteria:
- (a) it is listed in the European Inventory of Existing Commercial Chemical Substances (EINECS);
- (b) [^{F31}it was manufactured in the [^{F32}European Community], or in the countries acceding to the European Union on 1 January 1995, on 1 May 2004, on 1 January 2007 or on 1 July 2013, but not placed on the market by the manufacturer or importer, at least once in the 15 years before [^{F33}1 June 2007], provided the manufacturer or importer has documentary evidence of this;
- (c) it was placed on the market in the [^{F34}European Community], or in the countries acceding to the European Union on 1 January 1995, on 1 May 2004, on 1 January 2007 or on 1 July 2013, by the manufacturer or importer before [^{F35}1 June 2007] and it was considered as having been notified in accordance with the first indent of Article 8(1) of Directive 67/548/EEC in the version of Article 8(1) resulting from the amendment effected by Directive 79/831/EEC, but it does not meet the definition of a polymer as set out in this Regulation, provided the manufacturer or importer has documentary evidence of this, including proof that the substance was placed on the market by any manufacturer or importer between 18 September 1981 and 31 October 1993 inclusive;]
21. notified substance: means a substance for which a notification [^{F36}was] submitted and which could be placed on the market in accordance with Directive 67/548/EEC;
22. product and process orientated research and development: means any scientific development related to product development or the further development of a substance, on its own, in [^{F2}mixtures] or in articles in the course of which pilot plant or production trials are used to develop the production process and/or to test the fields of application of the substance;
23. scientific research and development: means any scientific experimentation, analysis or chemical research carried out under controlled conditions in a volume less than one tonne per year;

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24. use: means any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilisation;
25. registrant's own use: means an industrial or professional use by the registrant;
26. identified use: means a use of a substance on its own or in a [F²mixture], or a use of a [F²mixture], that is intended by an actor in the supply chain, including his own use, or that is made known to him in writing by an immediate downstream user;
27. full study report: means a complete and comprehensive description of the activity performed to generate the information. This covers the complete scientific paper as published in the literature describing the study performed or the full report prepared by the test house describing the study performed;
28. robust study summary: means a detailed summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an independent assessment of the study minimising the need to consult the full study report;
29. study summary: means a summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an assessment of the relevance of the study;
30. per year: means per calendar year, unless stated otherwise, for phase-in substances that have been imported or manufactured for at least three consecutive years, quantities per year shall be calculated on the basis of the average production or import volumes for the three preceding calendar years;
31. restriction: means any condition for or prohibition of the manufacture, use or placing on the market;
32. supplier of a substance or a [F²mixture]: means any manufacturer, importer, downstream user or distributor placing on the market a substance, on its own or in a [F²mixture], or a [F²mixture];
33. supplier of an article: means any producer or importer of an article, distributor or other actor in the supply chain placing an article on the market;
34. recipient of a substance or a [F²mixture]: means a downstream user or a distributor being supplied with a substance or a [F²mixture];
35. recipient of an article: means an industrial or professional user, or a distributor, being supplied with an article but does not include consumers;
36. SME: means small and medium-sized enterprises as defined in the Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises ⁽³⁾[F³⁷] and, in its application for the purposes of this paragraph, the Annex to that Recommendation has effect with the following modifications—
 - a in Article 2(1)—
 - i the reference to EUR 50 million has effect as a reference to £43.650 million;
 - ii the reference to EUR 43 million has effect as a reference to £37.539 million;

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- b in Article 2(2) the reference to EUR 10 million has effect as a reference to £8.730 million;
 - c in Article 2(3) the reference to EUR 2 million has effect as a reference to £1.746 million;
 - d in Article 3(2)—
 - i in point (a), the reference to EUR 1,250,000 has effect as a reference to £1,091,250;
 - ii in point (d), the reference to EUR 10 million has effect as a reference to £8.730 million;]
37. exposure scenario: means the set of conditions, including operational conditions and risk management measures, that describe how the substance is manufactured or used during its life-cycle and how the manufacturer or importer controls, or recommends downstream users to control, exposures of humans and the environment. These exposure scenarios may cover one specific process or use or several processes or uses as appropriate;
38. use and exposure category: means an exposure scenario covering a wide range of processes or uses, where the processes or uses are communicated, as a minimum, in terms of the brief general description of use;
39. substances which occur in nature: means a naturally occurring substance as such, unprocessed or processed only by manual, mechanical or gravitational means, by dissolution in water, by flotation, by extraction with water, by steam distillation or by heating solely to remove water, or which is extracted from air by any means;
40. not chemically modified substance: means a substance whose chemical structure remains unchanged, even if it has undergone a chemical process or treatment, or a physical mineralogical transformation, for instance to remove impurities;
41. alloy: means a metallic material, homogenous on a macroscopic scale, consisting of two or more elements so combined that they cannot be readily separated by mechanical means.
42. [^{F38}GB mandatory classification and labelling list: the list of mandatory classification and labelling requirements of substances and groups of substances established and maintained in accordance with Article 38A of Regulation (EC) No 1272/2008.]
43. [^{F38}GB notification database: the database established in accordance with Article 42 of Regulation (EC) No 1272/2008.]
44. [^{F39}relevant medical device: means 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;]

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, TITLE I. (See end of Document for details)

45. [F39 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.]

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).
- F21** Art. 3(A1)(A2) inserted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 4(2)** (as amended by S.I. 2020/1577, regs. 1(1)(b), **4(6)(a)(b)**); 2020 c. 1, Sch. 5 para. 1(1)
- F22** Words in Art. 3(4) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 4(3)** (as amended by S.I. 2020/1577, regs. 1(1)(b), **4(7)(a)(b)**); 2020 c. 1, Sch. 5 para. 1(1)
- F23** Words in Art. 3(9) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 4(4)** (as amended by S.I. 2020/1577, regs. 1(1)(b), **4(8)(a)(b)**); 2020 c. 1, Sch. 5 para. 1(1)
- F24** Words in Art. 3(10) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 4(5)** (as amended by S.I. 2020/1577, regs. 1(1)(b), **4(9)(a)(b)**); 2020 c. 1, Sch. 5 para. 1(1)
- F25** Art. 3(10A)(10B) inserted (31.12.2020) by S.I. 2019/758, reg. 1(1), **Sch. 1 para. 4(5A)** (as inserted by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1577), regs. 1(1)(b), **4(10)**); 2020 c. 1, Sch. 5 para. 1(1)
- F26** Words in Art. 3(11) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 4(6)** (as amended by S.I. 2020/1577, regs. 1(1)(b), **4(11)(a)(b)**); 2020 c. 1, Sch. 5 para. 1(1)
- F27** Words in Art. 3(13) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 4(6)** (as amended by S.I. 2020/1577, regs. 1(1)(b), **4(11)(a)(b)**); 2020 c. 1, Sch. 5 para. 1(1)
- F28** Words in Art. 3(14) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 4(6)** (as amended by S.I. 2020/1577, regs. 1(1)(b), **4(11)(a)(b)**); 2020 c. 1, Sch. 5 para. 1(1)
- F29** Art. 3(18)(18A) substituted for Art. 3(18) (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 4(7)**; 2020 c. 1, Sch. 5 para. 1(1)
- F30** Art. 3(19) 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. 4(8)**; 2020 c. 1, Sch. 5 para. 1(1)
- F31** Substituted by Council Regulation (EU) No 517/2013 of 13 May 2013 adapting certain regulations and decisions in the fields of free movement of goods, freedom of movement for persons, company law, competition policy, agriculture, food safety, veterinary and phytosanitary policy, transport policy, energy, taxation, statistics, trans-European networks, judiciary and fundamental rights, justice, freedom and security, environment, customs union, external relations, foreign, security and defence policy and institutions, by reason of the accession of the Republic of Croatia.
- F32** Words in Art. 3(20)(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. 4(9)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

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, TITLE I. (See end of Document for details)

- F33** Words in Art. 3(20)(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. 4(9)(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F34** Words in Art. 3(20)(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. 4(9)(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F35** Words in Art. 3(20)(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. 4(9)(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F36** Word in Art. 3(21) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 4(10)**; 2020 c. 1, Sch. 5 para. 1(1)
- F37** Words in Art. 3(36) inserted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 4(11)**; 2020 c. 1, Sch. 5 para. 1(1)
- F38** Art. 3(42)(43) inserted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 2** (as amended by S.I. 2020/1567, reg. 1(2), **Sch. 2 para. 2(a)**); 2020 c. 1, Sch. 5 para. 1(1)
- F39** Art. 3(44)(45) inserted (30.9.2021) by The REACH etc. (Amendment) Regulations 2021 (S.I. 2021/904), regs. 1(2), **3**

Article 4

General provision

Any manufacturer, importer, or where relevant downstream user, may, whilst retaining full responsibility for complying with his obligations under this Regulation, appoint a third party representative for all proceedings under Article 11, Article 19, Title III and Article 53 involving discussions with other manufacturers, importers, or where relevant downstream users. In these cases, the identity of a manufacturer or importer or downstream user who has appointed a representative shall not normally be disclosed by the Agency to other manufacturers, importers, or, where relevant, downstream users.

^{F40} Article 4A

The consent requirement

1 Where any provision of this Regulation states that a function is subject to the consent requirement in this Article, the function may be exercised in a particular instance only if the person exercising it has obtained the consent or consents (if any) required by paragraphs 2 to 4.

2 The consent of the Scottish Ministers is required if, or to the extent that, the exercise of the function is within devolved competence (within the meaning of section 54 of the Scotland Act 1998), whether or not the exercise of the function also relates to a part of Great Britain other than Scotland.

3. The consent of the Welsh Ministers is required if, or to the extent that, the exercise of the function is within devolved competence (within the meaning of section 58A(7) and (8) of the Government of Wales Act 2006) whether or not the exercise of the function also relates to a part of Great Britain other than Wales.]]

Textual Amendments

- F40** Art. 4A inserted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 5** (as amended by S.I. 2020/1577, regs. 1(1)(b), **4(12)(a)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

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, TITLE I . (See end of Document for details)

Modifications etc. (not altering text)

- C1** Art. 4A(1) modified (9.11.2021 for specified purposes, 28.2.2022 in so far as not already in force) by Environment Act 2021 (c. 30), s. 147(1)(b)(6), **Sch. 21 para. 3(2)** (with s. 144); S.R. 2022/54, art. 2(1) (p)

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 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).

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, TITLE I . (See end of Document for details)

- (1) [^{XI}OJ L 114, 27.4.2006, p. 9.]
- (2) [^{XI}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).]
- (3) [^{XI}OJ L 124, 20.5.2003, p. 36.]

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 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).

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, TITLE I .