

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>XI</sup> TITLE VII

### AUTHORISATION

#### CHAPTER 1

#### Authorisation requirement

##### *Article 55*

#### **Aim of authorisation and considerations for substitution**

The aim of this Title is to ensure the good functioning of the [<sup>F1</sup>market in Great Britain] while assuring that the risks from substances of very high concern are properly controlled and that these substances are progressively replaced by suitable alternative substances or technologies where these are economically and technically viable. To this end all manufacturers, importers and downstream users applying for authorisations shall analyse the availability of alternatives and consider their risks, and the technical and economic feasibility of substitution.

#### **Textual Amendments**

- F1** Words in *Art. 55* substituted (31.12.2020) by *The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758)*, reg. 1(1), **Sch. 1 para. 43** (as amended by *S.I. 2020/1577*, regs. 1(1)(b), **4(22)**); 2020 c. 1, Sch. 5 para. 1(1)

##### *Article 56*

#### **General provisions**

- 1 A manufacturer, importer or downstream user shall not place a substance on the market for a use or use it himself if that substance is included in Annex XIV, unless:
- a the use(s) of that substance on its own or in a [<sup>F2</sup>mixture] or the incorporation of the substance into an article for which the substance is placed on the market or for which he uses the substance himself has been authorised in accordance with Articles 60 to 64; or
  - b the use(s) of that substance on its own or in a [<sup>F2</sup>mixture] or the incorporation of the substance into an article for which the substance is placed on the market or for which

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- he uses the substance himself has been exempted from the authorisation requirement in Annex XIV itself in accordance with Article 58(2); or
- c the date referred to in Article 58(1)(c)(i) has not been reached; or
  - d the date referred to in Article 58(1)(c)(i) has been reached and he made an application 18 months before that date but a decision on the application for authorisation has not yet been taken; or
  - e in cases where the substance is placed on the market, authorisation for that use has been granted to his immediate downstream user.
- 2 A downstream user may use a substance meeting the criteria set out in paragraph 1 provided that the use is in accordance with the conditions of an authorisation granted to an actor up his supply chain for that use.
- 3 Paragraphs 1 and 2 shall not apply to the use of substances in scientific research and development. Annex XIV shall specify if paragraphs 1 and 2 apply to product and process orientated research and development as well as the maximum quantity exempted.
- 4 Paragraphs 1 and 2 shall not apply to the following uses of substances:
- a uses in plant protection products within the scope of [<sup>F3</sup>Regulation (EC) No 1107/2009];
  - b uses in biocidal products within the scope of [<sup>F4</sup>Regulation (EU) No 528/2012];
  - c use as motor fuels covered by [<sup>F5</sup>the Motor Fuel (Composition and Content) Regulations 1999];
  - d uses as fuel in mobile or fixed combustion plants of mineral oil products and use as fuels in closed systems.
- 5 In the case of substances that are subject to authorisation only because they meet the criteria in Article 57(a), (b) or (c) or because they are identified in accordance with Article 57(f) only because of hazards to human health, paragraphs 1 and 2 of this Article shall not apply to the following uses:
- a uses in cosmetic products within the scope of [<sup>F6</sup>Regulation (EC) No 1223/2009];
  - b uses in food contact materials within the scope of Regulation (EC) No 1935/2004.
- 6 Paragraphs 1 and 2 shall not apply to the use of substances when they are present in [<sup>F2</sup>mixtures]:
- a for substances referred to in Article 57(d), (e) and (f), below a concentration limit of 0,1 % weight by weight (w/w);
  - [<sup>F2</sup>b for all other substances, below the values specified in Article 11(3) of Regulation (EC) No 1272/2008 which result in the classification of the mixture as hazardous.]

#### 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. 56(4)(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. 44(2)(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F4** Words in Art. 56(4)(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. 44(2)(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F5** Words in Art. 56(4)(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. 44(2)(c)**; 2020 c. 1, Sch. 5 para. 1(1)

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**F6** Words in Art. 56(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. 44(3)**; 2020 c. 1, Sch. 5 para. 1(1)

### Article 57

#### Substances to be included in Annex XIV

The following substances may be included in Annex XIV in accordance with the procedure laid down in Article 58:

- (a) [<sup>F2</sup>substances meeting the criteria for classification in the hazard class carcinogenicity category 1A or 1B in accordance with section 3.6 of Annex I to Regulation (EC) No 1272/2008;
- (b) substances meeting the criteria for classification in the hazard class germ cell mutagenicity category 1A or 1B in accordance with section 3.5 of Annex I to Regulation (EC) No 1272/2008;
- (c) substances meeting the criteria for classification in the hazard class reproductive toxicity category 1A or 1B, adverse effects on sexual function and fertility or on development in accordance with section 3.7 of Annex I to Regulation(EC) No 1272/2008;]
- (d) substances which are persistent, bioaccumulative and toxic in accordance with the criteria set out in Annex XIII of this Regulation;
- (e) substances which are very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII of this Regulation;
- (f) substances — such as those having endocrine disrupting properties or those having persistent, bioaccumulative and toxic properties or very persistent and very bioaccumulative properties, which do not fulfil the criteria of points (d) or (e) — for which there is scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern to those of other substances listed in points (a) to (e) and which are identified on a case-by-case basis in accordance with the procedure set out in Article 59.

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

### Article 58

#### Inclusion of substances in Annex XIV

1 [<sup>F7</sup>The Secretary of State may, by regulations, include in Annex 14 substances referred to in Article 57. The regulations must specify for each substance:]

- a the identity of the substance as specified in Section 2 of Annex VI;
- b the intrinsic property (properties) of the substance referred to in Article 57;

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- c transitional arrangements:
  - (i) the date(s) from which the placing on the market and the use of the substance shall be prohibited unless an authorisation is granted (hereinafter referred to as the sunset date) which should take into account, where appropriate, the production cycle specified for that use;
  - (ii) a date or dates at least 18 months before the sunset date(s) by which applications must be received if the applicant wishes to continue to use the substance or place it on the market for certain uses after the sunset date(s); these continued uses shall be allowed after the sunset date until a decision on the application for authorisation is taken;
- d review periods for certain uses, if appropriate;
- e uses or categories of uses exempted from the authorisation requirement, if any, and conditions for such exemptions, if any.

2 Uses or categories of uses may be exempted from the authorisation requirement provided that, on the basis of the existing specific <sup>F8</sup>... legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substance, the risk is properly controlled. In the establishment of such exemptions, account shall be taken, in particular, of the proportionality of risk to human health and the environment related to the nature of the substance, such as where the risk is modified by the physical form.

3 Prior to a decision to include substances in Annex XIV, the Agency shall <sup>F9</sup>... recommend priority substances to be included specifying for each substance the items set out in paragraph 1. Priority shall normally be given to substances with:

- a PBT or vPvB properties; or
- b wide dispersive use; or
- c high volumes.

The number of substances included in Annex XIV and the dates specified under paragraph 1 shall also take account of the Agency's capacity to handle applications in the time provided for. The Agency shall make its first recommendation of priority substances to be included in Annex XIV [<sup>F10</sup>within 12 months of IP completion day]. The Agency shall make further recommendations at least every second year with a view to including further substances in Annex XIV.

4 Before the Agency sends its recommendation to the [<sup>F11</sup>appropriate authorities] it shall make it publicly available on its website, clearly indicating the date of publication, taking into account Articles 118 and 119 on access to information. The Agency shall invite all interested parties to submit comments within three months of the date of publication, in particular on uses which should be exempt from the authorisation requirement.

The Agency shall update its recommendation, taking into account the comments received.

5 Subject to paragraph 6, after inclusion of a substance in Annex XIV, this substance shall not be subjected to new restrictions under the procedure outlined in Title VIII covering the risks to human health or the environment from the use of the substance on its own, in a [<sup>F2</sup>mixture] or incorporation of a substance in an article arising from the intrinsic properties specified in Annex XIV.

6 A substance listed in Annex XIV may be subjected to new restrictions under the procedure outlined in Title VIII covering the risks to human health or the environment from the presence of the substance in (an) article(s).

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7 Substances for which all uses have been prohibited under Title VIII or by other <sup>F12</sup>... legislation shall not be included in Annex XIV or shall be removed from it.

[<sup>F13</sup> 8 The Secretary of State may, by regulations, remove from Annex 14 substances which as a result of new information no longer meet the criteria of Article 57.]

[<sup>F14</sup> 9 Regulations under paragraph 1 or 8 are to be made by statutory instrument; and a statutory instrument containing regulations under paragraph 1 or 8 is subject to annulment in pursuance of a resolution of either House of Parliament.

The function of making regulations under paragraph 1 or 8 is subject to the consent requirement in Article 4A.]

#### 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).
- F7** Words in Art. 58(1) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 45(2)**; 2020 c. 1, Sch. 5 para. 1(1)
- F8** Word in Art. 58(2) 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. 45(3)**; 2020 c. 1, Sch. 5 para. 1(1)
- F9** Words in Art. 58(3) 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. 45(4)(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F10** Words in Art. 58(3) substituted (31.12.2020) by virtue of S.I. 2019/758, **Sch. 1 para. 45(4)(b)** (as amended by The REACH etc. (Amendment etc.) (EU Exit) (No. 3) Regulations 2019 (S.I. 2019/1144), regs. 1, **3(3)** (as amended by S.I. 2020/1577, regs. 1(1)(a), **13(2)**) and S.I. 2020/1313, regs. 1(3), **6(2)**; 2020 c. 1, **Sch. 5 para. 1(1)**)
- F11** Words in Art. 58(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. 45(5)**; 2020 c. 1, Sch. 5 para. 1(1)
- F12** Word in Art. 58(7) 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. 45(6)**; 2020 c. 1, Sch. 5 para. 1(1)
- F13** Art. 58(8) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 45(7)**; 2020 c. 1, Sch. 5 para. 1(1)
- F14** Art. 58(9) inserted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 45(8)**; 2020 c. 1, Sch. 5 para. 1(1)

#### Article 59

##### Identification of substances referred to in Article 57

1 The procedure set out in paragraphs 2 to 10 of this Article shall apply for the purpose of identifying substances meeting the criteria referred to in Article 57 and establishing a candidate list for eventual inclusion in Annex XIV. The Agency shall indicate, within this list, the substances that are on its work programme according to Article 83(3)(e).

[<sup>F15</sup> 1A The Agency must include in its candidate list every substance that is included in ECHA's candidate list under Article 59(1) of EU REACH immediately before IP completion day.]

2 [<sup>F16</sup> An appropriate authority] may ask the Agency to prepare a dossier in accordance with relevant Sections of Annex XV for substances which in its opinion meet the criteria set out

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in Article 57. [<sup>F2</sup>The dossier may be limited, if appropriate, to a reference to an entry in [<sup>F17</sup>the GB mandatory classification and labelling list].] The Agency shall make this dossier available to the [<sup>F18</sup>appropriate authorities].

3 [<sup>F19</sup>The Agency] may prepare a dossier in accordance with Annex XV for substances which in its opinion meet the criteria set out in Article 57 <sup>F20</sup>.... [<sup>F2</sup>The dossier may be limited, if appropriate, to a reference to an entry in [<sup>F21</sup>the GB mandatory classification and labelling list].] The Agency shall make this dossier available [<sup>F22</sup>to the appropriate authorities].

4 The Agency shall publish on its website a notice that an Annex XV dossier has been prepared for a substance. The Agency shall invite all interested parties to submit comments within a specified deadline to the Agency.

<sup>F23</sup> 5 .....

6 If the Agency does not receive <sup>F24</sup>... any comments, it shall include this substance on the list referred to in paragraph 1. The Agency may include this substance in its recommendations under Article 58(3).

7 When comments are <sup>F25</sup>... received, the Agency [<sup>F26</sup>must consider the comments and make a decision on the identification of the substance within 45 days of the deadline specified in paragraph 4].

<sup>F27</sup> 8 .....

<sup>F27</sup> 9 .....

10 The Agency shall publish and update the list referred to in paragraph 1 on its website without delay after a decision on inclusion of a substance has been taken.

#### 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).
- F15** Art. 59(1A) inserted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 46(2)** (as amended by S.I. 2020/1313, regs. 1(3), **6(2)**); 2020 c. 1, Sch. 5 para. 1(1)
- F16** Words in Art. 59(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. 46(3)(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F17** Words in Art. 59(2) substituted (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. 4** (as amended by S.I. 2020/1567, reg. 1(2), **Sch. 2 para. 2(c)**); 2020 c. 1, Sch. 5 para. 1(1)
- F18** Words in Art. 59(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. 46(3)(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F19** Words in Art. 59(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. 46(4)(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F20** Words in Art. 59(3) 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. 46(4)(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F21** Words in Art. 59(3) substituted (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. 4** (as amended by S.I. 2020/1567, reg. 1(2), **Sch. 2 para. 2(c)**); 2020 c. 1, Sch. 5 para. 1(1)

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- F22** Words in Art. 59(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. 46(4)(c)**; 2020 c. 1, Sch. 5 para. 1(1)
- F23** Art. 59(5) 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. 46(5)**; 2020 c. 1, Sch. 5 para. 1(1)
- F24** Words in Art. 59(6) 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. 46(6)**; 2020 c. 1, Sch. 5 para. 1(1)
- F25** Words in Art. 59(7) 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. 46(7)(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F26** Words in Art. 59(7) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 46(7)(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F27** Art. 59(8)(9) 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. 46(8)**; 2020 c. 1, Sch. 5 para. 1(1)

## CHAPTER 2

### Granting of authorisations

#### Article 60

### Granting of authorisations

1 The [<sup>F28</sup>Secretary of State] shall be responsible for taking decisions on applications for authorisations in accordance with this Title. [<sup>F29</sup>That responsibility of the Secretary of State is subject to the provisions of this Title which make the exercise of certain functions subject to the consent requirement in Article 4A.]

2 Without prejudice to paragraph 3, an authorisation shall be granted if the risk to human health or the environment from the use of a substance arising from the intrinsic properties specified in Annex XIV is adequately controlled in accordance with Section 6.4 of Annex I and as documented in the applicant's chemical safety report, taking into account the opinion of the [<sup>F30</sup>Agency so far as the opinion relates to the elements] referred to in Article 64(4)(a). When granting the authorisation, and in any conditions imposed therein, the [<sup>F31</sup>Secretary of State] shall take into account all discharges, emissions and losses, including risks arising from diffuse or dispersive uses, known at the time of the decision.

The [<sup>F31</sup>Secretary of State] shall not consider the risks to human health arising from the use of a substance in a [<sup>F32</sup>relevant medical device].

3 Paragraph 2 shall not apply to:

- a substances meeting the criteria in Article 57(a), (b), (c) or (f) for which it is not possible to determine a threshold in accordance with Section 6.4 of Annex I;
- b substances meeting the criteria in Article 57(d) or (e);
- c substances identified under Article 57(f) having persistent, bioaccumulative and toxic properties or very persistent and very bioaccumulative properties.

4 If an authorisation cannot be granted under paragraph 2 or for substances listed in paragraph 3, an authorisation may only be granted if it is shown that socio-economic benefits outweigh the risk to human health or the environment arising from the use of the substance and if there are no suitable alternative substances or technologies. This decision shall be taken after consideration of all of the following elements and taking into account [<sup>F33</sup>the elements] referred to in Article 64(4)(a) and (b):

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- a the risk posed by the uses of the substance, including the appropriateness and effectiveness of the risk management measures proposed;
  - b the socio-economic benefits arising from its use and the socio-economic implications of a refusal to authorise as demonstrated by the applicant or other interested parties;
  - c the analysis of the alternatives submitted by the applicant under Article 62(4)(e) or any substitution plan submitted by the applicant under Article 62(4)(f), and any third party contributions submitted under Article 64(2);
  - d available information on the risks to human health or the environment of any alternative substances or technologies.
- 5 When assessing whether suitable alternative substances or technologies are available, all relevant aspects shall be taken into account by the [<sup>F34</sup>Secretary of State], including:
- a whether the transfer to alternatives would result in reduced overall risks to human health and the environment, taking into account the appropriateness and effectiveness of risk management measures;
  - b the technical and economic feasibility of alternatives for the applicant.
- 6 A use shall not be authorised if this would constitute a relaxation of a restriction set out in Annex XVII.
- 7 An authorisation shall be granted only if the application is made in conformity with the requirements of Article 62.
- 8 Authorisations shall be subject to a time-limited review without prejudice to any decision on a future review period and shall normally be subject to conditions, including monitoring. The duration of the time-limited review for any authorisation shall be determined on a case-by-case basis taking into account all relevant information including the elements listed in paragraph 4(a) to (d), as appropriate.
- 9 The authorisation shall specify:
- a the person(s) to whom the authorisation is granted;
  - b the identity of the substance(s);
  - c the use(s) for which the authorisation is granted;
  - d any conditions under which the authorisation is granted;
  - e the time-limited review period;
  - f any monitoring arrangement.
- 10 Notwithstanding any conditions of an authorisation, the holder shall ensure that the exposure is reduced to as low a level as is technically and practically possible.

#### Textual Amendments

- F28** Words in Art. 60(1) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 47(2)(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F29** Words in Art. 60(1) inserted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 47(2)(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F30** Words in Art. 60(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. 47(3)(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F31** Words in Art. 60(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. 47(3)(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F32** Words in Art. 60(2) substituted (30.9.2021) by The REACH etc. (Amendment) Regulations 2021 (S.I. 2021/904), regs. 1(2), 4

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- F33** Words in Art. 60(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. 47(4)**; 2020 c. 1, Sch. 5 para. 1(1)
- F34** Words in Art. 60(5) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 47(5)**; 2020 c. 1, Sch. 5 para. 1(1)

## Article 61

### Review of authorisations

1 Authorisations granted in accordance with Article 60 shall be regarded as valid until the [<sup>F35</sup>Secretary of State] decides to amend or withdraw the authorisation in the context of a review, provided that the holder of the authorisation submits a review report at least 18 months before the expiry of the time-limited review period. Rather than re-submitting all elements of the original application for the current authorisation, the holder of an authorisation may submit only the number of the current authorisation, subject to the second, third and fourth subparagraphs.

A holder of an authorisation granted in accordance with Article 60 shall submit an update of the analysis of alternatives referred to in Article 62(4)(e), including information about any relevant research and development activities by the applicant, if appropriate, and any substitution plan submitted under Article 62(4)(f). If the update of the analysis of alternatives shows that there is a suitable alternative available taking into account the elements in Article 60(5), he shall submit a substitution plan, including a timetable for proposed actions by the applicant. If the holder cannot demonstrate that the risk is adequately controlled, he shall also submit an update of the socio-economic analysis contained in the original application.

If he can now demonstrate that the risk is adequately controlled, he shall submit an update of the chemical safety report.

If any other elements of the original application have changed, he shall also submit updates of these element(s).

When any updated information is submitted in accordance with this paragraph, any decision to amend or withdraw the authorisation in the context of the review shall be taken in accordance with the procedure referred to in Article 64 applied *mutatis mutandis*.

[<sup>F36</sup>The function of deciding under this paragraph whether to amend or withdraw the authorisation is subject to the consent requirement in Article 4A.]

- 2 Authorisations may be reviewed at any time if:
- a the circumstances of the original authorisation have changed so as to affect the risk to human health or the environment, or the socio-economic impact; or
  - b new information on possible substitutes becomes available.

The [<sup>F37</sup>Secretary of State] shall set a reasonable deadline by which the holder(s) of the authorisation may submit further information necessary for the review and indicate by when it will take a decision in accordance with Article 64.

[<sup>F38</sup>Any of the other appropriate authorities may request the Secretary of State to carry out a review of an authorisation under this paragraph.]

3 In its review decision the [<sup>F39</sup>Secretary of State] may, if circumstances have changed and taking into account the principle of proportionality, amend or withdraw the authorisation,

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if under the changed circumstances it would not have been granted or if suitable alternatives in accordance with Article 60(5) become available. In the latter case the [F39Secretary of State] shall require the holder of the authorisation to present a substitution plan if he has not already done so as part of his application or update.

In cases where there is a serious and immediate risk for human health or the environment, the [F39Secretary of State] may suspend the authorisation pending the review, taking into account the principle of proportionality.

[F40Where the Secretary of State is carrying out a review of an authorisation under this paragraph, any of the other appropriate authorities may request the Secretary of State to suspend the authorisation while the review is being carried out.

The function of deciding under the first subparagraph whether to amend or withdraw the authorisation, and the function of deciding under the second subparagraph whether to suspend the authorisation, are subject to the consent requirement in Article 4A.]

4 If an environmental quality standard <sup>F41</sup>... is not met, the authorisations granted for the use of the substance concerned may be reviewed.

5 If the [F42river basin] environmental objectives <sup>F43</sup>... are not met, the authorisations granted for the use of the substance concerned in the relevant river basin may be reviewed.

6 If a use of a substance is subsequently prohibited or otherwise restricted in Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants <sup>(1)</sup>, the [F44Secretary of State] shall withdraw the authorisation for that use.

[F457 In this Article—

- a “environmental quality standard” means the set of requirements which must be fulfilled at a given time in relation to a given environment or particular part thereof, as set out in retained EU law;
- c “river basin district in Scotland” means an area designated as a river basin district by order under section 4(1) of the Water Environment and Water Services (Scotland) Act 2003;
- d “river basin environmental objectives” means—
  - i in relation to the Northumbria River Basin District, the environmental objectives referred to in the WFD Regulations as applied by regulation 5 of the Water Environment (Water Framework Directive) (Northumbria River Basin District) Regulations 2003;
  - ii in relation to the Solway Tweed River Basin District, the environmental objectives as defined in regulation 2 of the Water Environment (Water Framework Directive) (Solway Tweed River Basin District) Regulations 2004;
  - iii in relation to any other river basin district within the meaning of the WFD Regulations, the environmental objectives referred to in those Regulations;
  - iv in relation to a river basin district in Scotland, the environmental objectives set under section 9(1)(a) of the Water Environment and Water Services (Scotland) Act 2003;
- e “the WFD Regulations” means the Water Environment (Water Framework Directive) (England and Wales) Regulations 2017.]

#### Textual Amendments

**F35** Words in Art. 61(1) substituted (31.12.2020) by [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/758\)](#), reg. 1(1), [Sch. 1 para. 48\(2\)\(a\)](#); 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 VII. (See end of Document for details)

- F36** Words in Art. 61(1) inserted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 48(2)(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F37** Words in Art. 61(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. 48(3)(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F38** Words in Art. 61(2) inserted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 48(3)(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F39** Words in Art. 61(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. 48(4)(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F40** Words in Art. 61(3) inserted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 48(4)(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F41** Words in Art. 61(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. 48(5)**; 2020 c. 1, Sch. 5 para. 1(1)
- F42** Words in Art. 61(5) inserted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 48(6)(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F43** Words in Art. 61(5) 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. 48(6)(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F44** Words in Art. 61(6) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 48(7)**; 2020 c. 1, Sch. 5 para. 1(1)
- F45** Art. 61(7) inserted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 48(8)** (as amended by S.I. 2020/1577, regs. 1(1)(b), **4(23)**); 2020 c. 1, Sch. 5 para. 1(1)

## Article 62

### Applications for authorisations

- 1 An application for an authorisation shall be made to the Agency.
- 2 Applications for authorisation may be made by the manufacturer(s), importer(s) and/or downstream user(s) of the substance. Applications may be made by one or several persons.
- 3 Applications may be made for one or several substances, that meet the definition of a group of substances in Section 1.5 of Annex XI, and for one or several uses. Applications may be made for the applicant's own use(s) and/or for uses for which he intends to place the substance on the market.
- 4 An application for authorisation shall include the following information:
  - a the identity of the substance(s), as referred to in Section 2 of Annex VI;
  - b the name and contact details of the person or persons making the application;
  - c a request for authorisation, specifying for which use(s) the authorisation is sought and covering the use of the substance in [F<sup>2</sup>mixtures] and/or the incorporation of the substance in articles, where this is relevant;
  - d unless already submitted as part of the registration, a chemical safety report in accordance with Annex I covering the risks to human health and/or the environment from the use of the substance(s) arising from the intrinsic properties specified in Annex XIV;
  - e an analysis of the alternatives considering their risks and the technical and economic feasibility of substitution and including, if appropriate information about any relevant research and development activities by the applicant;
  - f where the analysis referred to in point (e) shows that suitable alternatives are available, taking into account the elements in Article 60(5), a substitution plan including a timetable for proposed actions by the applicant.

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- 5 The application may include:
- a a socio-economic analysis conducted in accordance with Annex XVI;
  - b a justification for not considering risks to human health and the environment arising either from:
    - i emissions of a substance from an installation for which a permit <sup>F46</sup>to carry out an activity referred to in Annex I to Directive 2010/75/EU was granted in accordance with retained EU law]; or
    - <sup>F47</sup>ii discharges of a substance from a point source governed by retained EU law that transposed the requirement for prior regulation referred to in Article 11(3)(g) of Directive 2000/60/EC and Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy.]
- 6 The application shall not include the risks to human health arising from the use of a substance in a <sup>F48</sup>relevant medical device].
- 7 An application for an authorisation shall be accompanied by the fee required in accordance with Title IX.

#### 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 \(Text with EEA relevance\).](#)
- F46** Words in Art. 62(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. 49(2)(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F47** Art. 62(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. 49(2)(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F48** Words in Art. 62(6) substituted (30.9.2021) by [The REACH etc. \(Amendment\) Regulations 2021 \(S.I. 2021/904\)](#), regs. 1(2), **5**

### Article 63

#### Subsequent applications for authorisation

- 1 If an application has been made for a use of a substance, a subsequent applicant may refer to the appropriate parts of the previous application submitted in accordance with Article 62(4)(d), (e) and (f) and (5)(a), provided that the subsequent applicant has permission from the previous applicant to refer to these parts of the application.
- 2 If an authorisation has been granted for a use of a substance, a subsequent applicant may refer to the appropriate parts of the previous application submitted in accordance with Article 62(4)(d), (e) and (f) and (5)(a), provided that the subsequent applicant has permission from the holder of the authorisation to refer to these parts of the application.
- 3 Before referring to any previous application in accordance with paragraphs 1 and 2, the subsequent applicant shall update the information of the original application as necessary.

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## Article 64

### Procedure for authorisation decisions

1 The Agency shall acknowledge the date of receipt of the application. [F49The Agency must give its draft opinion within ten months of the date of receipt of the application].

2 The Agency shall make available on its web-site broad information on uses, taking into account Articles 118 and 119 on access to information, for which applications have been received and for reviews of authorisations, with a deadline by which information on alternative substances or technologies may be submitted by interested third parties.

[F50 3 In preparing its opinion, the Agency must first check that the application includes all the information specified in Article 62 that is relevant to its remit. If necessary, the Agency must request additional information to bring the application into conformity with the requirements of Article 62. The Agency may, if it deems it necessary, require the applicant or request third parties to submit, within a specified time period, additional information on possible alternative substances or technologies. The Agency, and any scientific adviser providing the Agency with scientific knowledge and advice in relation to the opinion, must take into account any information submitted by third parties.]

[F513A In paragraph 3 “scientific adviser” means a person who the Agency has commissioned (in compliance with the duty imposed by Article 77(A1)) to provide it with scientific knowledge and advice.]

4 The draft [F52opinion] shall include the following elements:

- a [F53... An assessment of the risk to human health and/or the environment arising from the use(s) of the substance, including the appropriateness and effectiveness of the risk management measures as described in the application and, if relevant, an assessment of the risks arising from possible alternatives;
- b [F54... An assessment of the socio-economic factors and the availability, suitability and technical feasibility of alternatives associated with the use(s) of the substance as described in the application, when an application is made in accordance with Article 62 and of any third party contributions submitted under paragraph 2 of this Article.

5 The Agency shall send [F55:its draft opinion] to the applicant by the end of the deadline set out in paragraph 1. Within one month of receipt of the draft opinion, the applicant may provide written notice that he wishes to comment. The draft opinion shall be deemed to have been received seven days after the Agency has sent it.

If the applicant does not wish to comment, the Agency shall send [F56:its final opinion to the appropriate authorities] and the applicant, within 15 days of the end of the period within which the applicant may comment or within 15 days of receipt of notice from the applicant that he does not intend to comment.

If the applicant wishes to comment, he shall send his written argumentation to the Agency within two months of the receipt of the draft opinion. The [F57Agency] shall consider the comments and adopt [F58:its] final [F59opinion] within two months of receipt of the written argumentation, taking this argumentation into account where appropriate. Within a further 15 days the Agency shall send the [F59opinion], with the written argumentation attached, to the [F60appropriate authorities] and the applicant.

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6 The Agency shall determine in accordance with Articles 118 and 119 which parts of its [<sup>F61</sup>opinion] and parts of any attachments thereto should be made publicly available on its website.

7 In cases covered by Article 63(1), the Agency shall treat the applications together, provided the deadlines for the first application can be met.

[<sup>F62</sup> 8 The Secretary of State must make a decision granting or refusing the authorisation within six months of receipt of the opinion from the Agency.

The function in this paragraph of deciding whether to grant or refuse the authorisation is subject to the consent requirement in Article 4A.]

9 Summaries of the [<sup>F63</sup>decisions of the Secretary of State], including the authorisation number and the reasons for the decision, in particular where suitable alternatives exist, shall be published [<sup>F64</sup>by the Secretary of State] and shall be made publicly available in a database established and kept up to date by the Agency.

10 In cases covered by Article 63(2), the deadline set out in paragraph 1 of this Article shall be shortened to five months.

#### Textual Amendments

- F49** Words in Art. 64(1) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 50(2)**; 2020 c. 1, Sch. 5 para. 1(1)
- F50** Art. 64(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. 50(3)**; 2020 c. 1, Sch. 5 para. 1(1)
- F51** Art. 64(3A) inserted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 50(4)**; 2020 c. 1, Sch. 5 para. 1(1)
- F52** Word in Art. 64(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. 50(5)(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F53** Words in Art. 64(4)(a) 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. 50(5)(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F54** Words in Art. 64(4)(b) 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. 50(5)(c)**; 2020 c. 1, Sch. 5 para. 1(1)
- F55** Words in Art. 64(5) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 50(6)(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F56** Words in Art. 64(5) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 50(6)(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F57** Word in Art. 64(5) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 50(6)(c)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F58** Word in Art. 64(5) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 50(6)(c)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F59** Word in Art. 64(5) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 50(6)(c)(iii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F60** Words in Art. 64(5) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 50(6)(c)(iv)**; 2020 c. 1, Sch. 5 para. 1(1)
- F61** Word in Art. 64(6) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 50(7)**; 2020 c. 1, Sch. 5 para. 1(1)
- F62** Art. 64(8) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 50(8)**; 2020 c. 1, Sch. 5 para. 1(1)
- F63** Words in Art. 64(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. 50(9)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

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**F64** Words in Art. 64(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. 50(9)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

## CHAPTER 3

### Authorisations in the supply chain

#### Article 65

#### Obligation of holders of authorisations

Holders of an authorisation, as well as downstream users referred to in Article 56(2) including the substances in a [<sup>F2</sup>mixture], shall include the authorisation number on the label before they place the substance or a [<sup>F2</sup>mixture] containing the substance on the market for an authorised use <sup>F65</sup>.... This shall be done without delay once the authorisation number has been made publicly available in accordance with Article 64(9).

#### 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).
- F65** Words in Art. 65 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. 51**; 2020 c. 1, Sch. 5 para. 1(1)

#### Article 66

#### Downstream users

1 Downstream users using a substance in accordance with Article 56(2) shall notify the Agency within three months of the first supply of the substance.

2 The Agency shall establish and keep up to date a register of downstream users who have made a notification in accordance with paragraph 1. The Agency shall grant access to this register to the [<sup>F66</sup>appropriate authorities].]

#### Textual Amendments

- F66** Words in Art. 66(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. 52**; 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 158, 30.4.2004, p. 7, corrected in OJ L 229, 29.6.2004, p. 5. Regulation as amended by Council Regulation (EC) No 1195/2006 (OJ L 217, 8.8.2006, p. 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 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:**

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