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 VII

AUTHORISATION

CHAPTER 2

Granting of authorisations

[X1 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 **[**F1mixtures**]** 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.

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 **[**F2to carry out an activity referred to in Annex I to Directive 2010/75/EU was granted in accordance with retained EU law**]**; or

[F3ii 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 **[**F4relevant medical device**]**.

7 An application for an authorisation shall be accompanied by the fee required in accordance with Title IX. **]**

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).

Textual Amendments

F1 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).

F2 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)

F3 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)

F4 Words in Art. 62(6) substituted (30.9.2021) by The REACH etc. (Amendment) Regulations 2021 (S.I. 2021/904), regs. 1(2), **5**

Status:
Point in time view as at 30/09/2021.

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, Article 62 .