

Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents (Text with EEA relevance)

*Article 5*

**Granting of derogation**

1 The request by a manufacturer for derogation shall be made by sending an application to the competent authority of the Member State concerned, referred to in Article 8(1), and to the Commission, providing evidence relating to the criteria mentioned under Article 6(1). Member States can make the request for derogation dependent upon the payment to the Member State's competent authority of a fee. Such fees, if any, shall be levied in a non-discriminatory way and shall not exceed the cost of processing the application.

2 Applications shall include a technical file supplying all the information and justifications necessary for evaluating the safety aspects related to the specific use of surfactants in detergents failing to comply with the biodegradability limits, as set out in Annex III.

In addition to the results of tests stipulated in Annex III, the technical file shall include information and results of tests, as stipulated in Annexes II and IV.

The tests laid down in Annex IV, point 4 shall be carried out on the basis of a tiered approach. The tiered approach will be defined in a technical guidance document to be adopted in accordance with the procedure referred to in Article 12(2) by 8 April 2007. This guidance document will also specify, where appropriate, those tests for which the principles of good laboratory practice should be applied.

3 The competent authority of the Member State, receiving applications for derogation in accordance with paragraphs 1 and 2, shall examine the requests, evaluate their compliance with the conditions for derogation and inform the Commission about the results within six months of receiving the complete application.

If the competent authority of the Member State deems it necessary for the evaluation of the risk which may be caused by a substance and/or a [<sup>F1</sup>mixture], it shall, within three months of receiving the application, ask for further information, verification and/or confirmatory tests concerning these substances and/or [<sup>F1</sup>mixtures] or their transformation products, of which they have been notified or have received information under this Regulation. The time period for the evaluation of the dossier by the competent authority of the Member State will start only after the dossier is completed with the additional information. If the requested information is not provided within 12 months, the application shall be considered incomplete and thus invalid. In such a case Article 6(2) shall not apply.

If further information on metabolites is sought, stepwise testing strategies should be employed to ensure maximum use of in-vitro and other non-animal test methods.

4 On the basis of, in particular, the evaluation carried out by the Member State, the Commission may grant a derogation in accordance with the procedure referred to in Article 12(2). If necessary, before granting such derogation the Commission shall evaluate further the matters indicated in paragraph 3 of this Article. It shall take its decision within 12 months of receiving the evaluation from the Member State, except in the case of Article 5(4) and (6) of Decision 1999/468/EC where the period shall be 18 months.

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**Changes to legislation:** There are outstanding changes not yet made to Regulation (EC) No 648/2004 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) [View outstanding changes](#)

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5 Such derogations may allow, limit or severely restrict the placing on the market and the use of surfactants as ingredients in detergents, depending on the results of the complementary risk assessment, as defined in Annex IV. They may include a phase-out period for placing on the market and the use of surfactants as ingredients in detergents. The Commission may review a derogation as soon as information comes to light which would justify a significant revision of the technical file that was included in the application for derogation. For this purpose, the manufacturer shall, upon request, supply to the Commission a technical file that has been updated regarding the items mentioned in Annex IV, point 2. On the basis of this updated information, the Commission may decide to prolong, modify or terminate the derogation. Paragraphs 1 to 4 and 6 of this Article and Article 6 shall apply *mutatis mutandis*.

6 The Commission shall publish the list of surfactants that have obtained derogation, with the corresponding conditions or limitations of use, as provided in Annex V.

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#### **Textual Amendments**

- F1** Substituted by [Regulation \(EC\) No 1336/2008 of the European Parliament and of the Council of 16 December 2008 amending Regulation \(EC\) No 648/2004 in order to adapt it to Regulation \(EC\) No 1272/2008 on classification, labelling and packaging of substances and mixtures \(Text with EEA relevance\)](#).

### Changes to legislation:

There are outstanding changes not yet made to Regulation (EC) No 648/2004 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations.

[View outstanding changes](#)

#### Changes and effects yet to be applied to :

- Art. 5(1) words omitted by [S.I. 2019/672 reg. 8\(2\)\(a\)](#)
- Art. 5(1) words omitted by [S.I. 2019/672 reg. 8\(2\)\(b\)\(ii\)](#)
- Art. 5(1) words substituted by [S.I. 2019/672 reg. 8\(2\)\(b\)\(i\)](#)
- Art. 5(2) words omitted by [S.I. 2019/672 reg. 8\(3\)\(b\)](#)
- Art. 5(2) words substituted by [S.I. 2019/672 reg. 8\(3\)\(a\)](#)
- Art. 5(3) word substituted by [S.I. 2019/672 reg. 8\(4\)\(a\)\(ii\)](#)
- Art. 5(3) words omitted by [S.I. 2019/672 reg. 8\(4\)\(a\)\(i\)](#)
- Art. 5(3) words omitted by [S.I. 2019/672 reg. 8\(4\)\(a\)\(iii\)](#)
- Art. 5(3) words omitted by [S.I. 2019/672 reg. 8\(4\)\(b\)\(i\)](#)
- Art. 5(3) words omitted by [S.I. 2019/672 reg. 8\(4\)\(b\)\(ii\)](#)
- Art. 5(4) words omitted by [S.I. 2019/672 reg. 8\(5\)\(a\)\(ii\)](#)
- Art. 5(4) words omitted by [S.I. 2019/672 reg. 8\(5\)\(b\)](#)
- Art. 5(4) words substituted by [S.I. 2019/672 reg. 8\(5\)\(a\)\(i\)](#)
- Art. 5(4) words substituted by [S.I. 2019/672 reg. 8\(5\)\(c\)](#)
- Art. 5(5) words substituted by [S.I. 2019/672 reg. 8\(6\)](#)
- Art. 5(6) words substituted by [S.I. 2019/672 reg. 8\(6\)](#)

#### Changes and effects yet to be applied to the whole legislation item and associated provisions

- Signature words omitted by [S.I. 2019/672 reg. 22](#)
- Annex 1 para. 1 words substituted by [S.I. 2019/672 reg. 23\(2\)\(a\)](#)
- Annex 1 para. 1 words substituted by [S.I. 2019/672 reg. 23\(2\)\(b\)](#)
- Annex 1 para. 1 words substituted by [S.I. 2019/672 reg. 23\(2\)\(c\)](#)
- Annex 1 para. 2 words substituted by [S.I. 2019/672 reg. 23\(3\)\(a\)](#)
- Annex 1 para. 2 words substituted by [S.I. 2019/672 reg. 23\(3\)\(b\)](#)
- Annex 2 s. A words substituted by [S.I. 2019/672 reg. 24\(2\)](#)
- Annex 2 s. B words substituted by [S.I. 2019/672 reg. 24\(2\)](#)
- Annex 2 s. D words substituted by [S.I. 2019/672 reg. 24\(2\)](#)
- Annex 2 s. C words substituted by [S.I. 2019/672 reg. 24\(3\)](#)
- Art. 2(9) word omitted by [S.I. 2019/672 reg. 6\(2\)\(a\)](#)
- Art. 2(9) words substituted by [S.I. 2019/672 reg. 6\(2\)\(b\)](#)
- Art. 2(9) words substituted by [S.I. 2019/672, reg. 6\(2\) \(as substituted\) by S.I. 2020/1617 reg. 2\(4\)\(a\)](#)
- Art. 2(9a) words substituted by [S.I. 2019/672 reg. 6\(3\)](#)
- Art. 2(9A) words substituted in earlier amending provision [S.I. 2019/672, reg. 6\(3\) by S.I. 2020/1617 reg. 2\(4\)\(b\)](#)
- Art. 2(10) words inserted by [S.I. 2019/672 reg. 6\(4\)](#)
- Art. 2(10) words inserted by [S.I. 2019/672, reg. 6\(4\) \(as substituted\) by S.I. 2020/1617 reg. 2\(4\)\(c\)](#)
- Art. 2(13)-(15) inserted by [S.I. 2019/672 reg. 6\(5\)](#)
- Art. 2(16) inserted in earlier amending provision [S.I. 2019/672, reg. 6\(5\) by S.I. 2020/1617 reg. 2\(4\)\(d\)](#)
- Annex 3 Pt. B words omitted by [S.I. 2019/672 reg. 25\(3\)\(c\)](#)
- Annex 3 Pt. A para. 2 words substituted by [S.I. 2019/672 reg. 25\(2\)\(a\)](#)
- Annex 3 Pt. A para. 3 words substituted by [S.I. 2019/672 reg. 25\(2\)\(b\)](#)
- Annex 3 Pt. A para. 4 words substituted by [S.I. 2019/672 reg. 25\(2\)\(c\)](#)
- Annex 3 Pt. A para. 5 words substituted by [S.I. 2019/672 reg. 25\(2\)\(d\)](#)
- Annex 3 Pt. B para. 1 words substituted by [S.I. 2019/672 reg. 25\(3\)\(a\)](#)

- Annex 3 Pt. B para. 2 words substituted by [S.I. 2019/672 reg. 25\(3\)\(b\)](#)
- Art. 3(1)(a) substituted by [S.I. 2019/672 reg. 7\(2\)\(b\)](#)
- Art. 3(1)(a) words substituted in earlier amending provision S.I. 2019/672, reg. 7(2)(b) by [S.I. 2020/1617 reg. 2\(5\)](#)
- Art. 3(1)(b) words substituted by [S.I. 2019/672 reg. 7\(2\)\(c\)](#)
- Art. 3(1)(c) words substituted by [S.I. 2019/672 reg. 7\(2\)\(d\)](#)
- Art. 3A inserted by S.I. 2019/672, reg. 7A (as inserted) by [S.I. 2020/1617 reg. 2\(6\)](#)
- Annex 4 point 3 words inserted by [S.I. 2019/672 reg. 26\(8\)\(b\)](#)
- Annex 4 words omitted by [S.I. 2019/672 reg. 26\(6\)](#)
- Annex 4 point 1 heading words omitted by [S.I. 2019/672 reg. 26\(7\)](#)
- Annex 4 point 3 words omitted by [S.I. 2019/672 reg. 26\(8\)\(a\)](#)
- Annex 4 words omitted by [S.I. 2019/672 reg. 26\(13\)](#)
- Annex 4 words substituted by [S.I. 2019/672 reg. 26\(2\)](#)
- Annex 4 words substituted by [S.I. 2019/672 reg. 26\(3\)](#)
- Annex 4 words substituted by [S.I. 2019/672 reg. 26\(4\)](#)
- Annex 4 words substituted by [S.I. 2019/672 reg. 26\(5\)](#)
- Annex 4 point 4.1.2 words substituted by [S.I. 2019/672 reg. 26\(9\)\(a\)](#)
- Annex 4 point 4.1.2 words substituted by [S.I. 2019/672 reg. 26\(9\)\(b\)](#)
- Annex 4 point 4.1.3 words substituted by [S.I. 2019/672 reg. 26\(10\)](#)
- Annex 4 point 4.2.2 words substituted by [S.I. 2019/672 reg. 26\(11\)\(a\)](#)
- Annex 4 point 4.2.2 words substituted by [S.I. 2019/672 reg. 26\(11\)\(b\)](#)
- Annex 4 point 4.2.2 words substituted by [S.I. 2019/672 reg. 26\(11\)\(c\)](#)
- Annex 4 point 4.2.2 words substituted by [S.I. 2019/672 reg. 26\(11\)\(d\)](#)
- Annex 4 point 4.2.3 words substituted by [S.I. 2019/672 reg. 26\(12\)\(a\)](#)
- Annex 4 point 4.2.3 words substituted by [S.I. 2019/672 reg. 26\(12\)\(b\)](#)
- Annex 5 words omitted by [S.I. 2019/672 reg. 27](#)
- Annex 7 Pt. B words inserted by [S.I. 2019/672 reg. 28\(3\)\(b\)](#)
- Annex 7 Pt. A words substituted by [S.I. 2019/672 reg. 28\(2\)\(a\)\(i\)](#)
- Annex 7 Pt. A words substituted by [S.I. 2019/672 reg. 28\(2\)\(a\)\(ii\)](#)
- Annex 7 Pt. A words substituted by [S.I. 2019/672 reg. 28\(2\)\(b\)\(i\)](#)
- Annex 7 Pt. A words substituted by [S.I. 2019/672 reg. 28\(2\)\(b\)\(ii\)](#)
- Annex 7 Pt. B words substituted by [S.I. 2019/672 reg. 28\(3\)\(a\)](#)
- Annex 7 Pt. C words substituted by [S.I. 2019/672 reg. 28\(4\)](#)
- Annex 7 Pt. D words substituted by [S.I. 2019/672 reg. 28\(5\)](#)
- Annex 8 words substituted by [S.I. 2019/672 reg. 29](#)
- Art. 10(3)(4) inserted by [S.I. 2019/672 reg. 13\(4\)](#)
- Art. 15(3)-(8) inserted by [S.I. 2019/671 reg. 3\(4\)](#)
- Art. 15(3) words omitted in earlier amending provision S.I. 2019/671, reg. 3(4) by [S.I. 2020/1617 reg. 3\(2\)\(b\)\(i\)](#)
- Art. 15(6)(7) omitted in earlier amending provision S.I. 2019/671, reg. 3(4) by [S.I. 2020/1617 reg. 3\(2\)\(b\)\(ii\)](#)
- Art. 18A inserted by [S.I. 2019/672 reg. 21](#)
- Art. 18A(1) words omitted in earlier amending provision S.I. 2019/672, reg. 21 by [S.I. 2020/1617 reg. 2\(9\)\(a\)](#)
- Art. 18A(3) substituted in earlier amending provision S.I. 2019/672, reg. 21 by [S.I. 2020/1617 reg. 2\(9\)\(b\)](#)