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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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## ANNEX IV

### COMPLEMENTARY RISK ASSESSMENT FOR SURFACTANTS IN DETERGENTS

For those surfactants for which an environmental risk assessment is available in the context of Directive 93/67/EEC, or Regulation (EEC) No 793/93 and Regulation (EC) No 1488/94, and Technical Guidance Documents, this risk assessment shall be considered together with the complementary risk assessment run in the scope of this Regulation.

The complementary risk assessment run in the scope of this Regulation, in case it is likely that recalcitrant metabolites are produced, shall be considered in the context of assessments made on the basis of Directive 93/67/EEC or Regulation (EEC) No 793/93. This is to be assessed case by case and in particular on the basis of the results of the tests referred to in part 3.

The study shall cover the aquatic environmental compartment. Additional information relating to specific risk assessment concerns might be required by the Committee referred to in Article 12(2) on a case by case basis. Additional information might include other environmental compartments such as sewage sludge and soil. A tiered approach shall be adopted concerning the information required for the technical file referred to in Articles 5 and 9. The file shall contain at least the information described under points 1, 2 and 3 below.

However, to minimise testing, and especially to avoid unnecessary animal testing, the additional studies listed under point 4.2.2 should be requested only where such information is necessary and proportionate. In case of dispute concerning the extent of additional information required, a Decision may be taken in accordance with the procedure laid down in Article 12(2).

As noted in Article 13, the guidelines included in this Annex for the Decisions on derogation may be adapted as appropriate on the basis of the accumulated experience.

1. Identity of the surfactant (in accordance with the provisions laid down by Annex VII.A of Directive 67/548/EEC).
  - 1.1. Name
    - 1.1.1. Names in the IUPAC nomenclature
    - 1.1.2. Other names
    - 1.1.3. CAS number and CAS name (if available)
    - 1.1.4. Eines<sup>(1)</sup> or Elines<sup>(2)</sup> numbers (if available)
  - 1.2. Molecular and structural formula
  - 1.3. Composition of the surfactant
2. Information on the surfactant
  - 2.1. Quantities of the surfactant used in detergents
  - 2.2. The information on use patterns given in this section shall be sufficient to allow an approximate but realistic estimate of function and environmental exposure to the surfactant as associated with its use in detergents. It shall include the following:
    - importance of the application (societal value),
    - use conditions (release scenario),
    - use volume,
    - availability and suitability of alternatives (performance and economic considerations),

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— assessment of relevant environmental information.

### 3. Information on the potential recalcitrant metabolites

Toxicity information on test liquors shall be provided. If no data are available on residue identity, the information referred to in point 4.2.1 may be requested, depending on the potential risk, the importance and the quantity of the surfactant used in detergents. In conflicting cases concerning this information, a Decision may be taken in accordance with the procedure laid down in Article 12(2).

### 4. Additional studies

#### 4.1. Biodegradability tests

##### 4.1.1. Pre-adapted inoculum

Any of the tests described in Annex III, may be run with pre adapted inoculum in order to provide evidence of the relevance of pre-adaptation for the surfactant.

##### 4.1.2. Inherent Biodegradability Tests

At least one of the tests referred to below shall be included:

- method of the Directive 67/548/EEC, Annex V.C.12 (Modified SCAS test),
- method of the Directive 67/548/EEC, Annex V.C.9 (Zahn-Wellens).

Failure to pass the inherent biodegradability test would indicate potential for persistency which may be considered, in general terms, as sufficient to prohibit the placing on the market of such a surfactant except in cases where the criteria set out in Article 6 indicate that there is no justification for refusing a derogation.

##### 4.1.3. Activated Sludge Simulation Biodegradability Tests

The following tests referred below shall be included:

- method of the Directive 67/548/EEC, Annex V.C.10 (including possible changes in operating conditions as proposed in EN ISO 11733).

Failure to pass the activated sludge simulation biodegradability test would indicate potential for the release of the metabolites by sewage treatment, which may be considered, in general terms, as evidence of need for a more complete risk assessment.

### 4.2. Toxicity testing of biodegradation test liquors

Toxicity information on test liquors is to be provided on:

#### 4.2.1. Chemical and physical information, such as:

- identity of the metabolite (and analytical means by which it was obtained);
- key physical chemical properties (water solubility, Octanol: Water partition coefficient (Log Po/w, etc.).

#### 4.2.2. Effects on organisms. Tests to be conducted in compliance with the principles of good laboratory practice.

Fish: the test recommended is that in Annex V.C.1 of Directive 67/548/EEC

Daphnia: the test recommended is that in Annex V.C.2 of Directive 67/548/EEC

Algae: the test recommended is that in Annex V.C.3 of Directive 67/548/EEC

Bacteria: the test recommended is that in Annex V.C.11 of Directive 67/548/EEC

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#### 4.2.3. Degradation

Biotic: the test recommended is that in Annex V.C.5 of Directive 67/548/EEC

Abiotic: the test recommended is that in Annex V.C.7 of Directive 67/548/EEC. The information to be provided will consider as well the potential of metabolites for bio-concentration and their partitioning to the sediment phase.

Moreover, if some metabolites are suspected for endocrine disrupting activity, it is recommended to determine if these have potential to result in adverse effects as soon as validated testing schemes to assess such adverse effects are available.

N.B.

All the abovementioned tests can also be consulted in the publication Classification, Packaging and Labelling of Dangerous Substances in the European Union; Part 2: 'Testing Methods'. European Commission 1997. ISBN 92-828-0076-8.

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- (1) European Inventory of Existing Commercial Substances.
- (2) European List of Notified Chemical Substances.

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### 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\(9\)\(b\)](#)