
DRAFT STATUTORY INSTRUMENTS

2019 No. 0000

EXITING THE EUROPEAN UNION

CONSUMER PROTECTION

ENVIRONMENTAL PROTECTION

PUBLIC HEALTH

The Detergents (Amendment) (EU Exit) Regulations 2019

Made - - - - - *******

Coming into force in accordance with regulation 1

The Secretary of State makes these Regulations in exercise of the powers conferred by section 8(1) of, and paragraph 21 of Schedule 7 to, the European Union (Withdrawal) Act 2018^(a).

In accordance with paragraph 1(1) of Schedule 7 to that Act, a draft of this instrument has been laid before Parliament and approved by a resolution of each House of Parliament.

PART 1

Introduction

Citation and commencement

1. These Regulations may be cited as the Detergents (Amendment) (EU Exit) Regulations 2019 and come into force on the later of exit day or the day after the day on which they are made.

PART 2

Amendment of subordinate legislation

Amendment of the Detergents Regulations 2010

- 2.—(1) The Detergents Regulations 2010(a) are amended as follows.
- (2) In regulation 2(1)—
- (a) at the appropriate place, insert—
- ““application for derogation” means a request for derogation made under Article 4(2) of Regulation 648/2004;”;
- (b) omit the definition of “Commission Recommendation”.
- (3) Omit regulation 3.
- (4) In regulation 4(5)—
- (a) in sub-paragraph (a), for “regulation 3(1)”, substitute “Articles 8 and 15(1) of Regulation 648/2004;”;
- (b) in sub-paragraph (b), for “regulation 3(2)”, substitute “Article 9(3) of that Regulation”.
- (5) Omit regulation 6.
- (6) In regulation 7, for paragraph 1, substitute “Any manufacturer who places on the market any controlled product is guilty of an offence unless the controlled product conforms with Article 3(1) of Regulation 648/2004.”.
- (7) In regulation 8, omit paragraphs (1) and (2).
- (8) In regulation 11(1), for “regulation 6 or 7 or of a directly applicable”, substitute “regulation 7 or a”.
- (9) In regulation 12(1), for “regulations 6 or 7 or a directly applicable”, substitute “regulation 7 or a”.
- (10) In regulation 13, for “regulations 6 or 7 or of a directly applicable”, substitute “regulation 7 or a”.
- (11) In Schedule 2, in the table—
- (a) in the row for which the entry in the first column is “Article 3”, in the second column under the heading “*Subject matter*”, omit “and (2)”;
- (b) in the row for which the entry in the first column is “Article 11(5)”, in the second column under the heading “*Subject matter*”, for “the national language of the member State”, substitute “English”.

PART 3

Amendment of retained direct EU legislation

Interpretation

3. In this Part—

“Contracting Parties” has the meaning given to that expression in the EEA agreement;

“Regulation (EC) No 648/2004” means—

- (a) Regulation (EC) No 648/2004 of the European Parliament and of the Council on detergents;

(a) S.I. 2010/740, amended by S.I. 2013/1244; there is another amending instrument but it is not relevant.

- (b) the corresponding act made part of the internal legal order of the Contracting Parties under Article 7(a) of the EEA agreement^(a).

Amendment of Regulation (EC) No 648/2004

4. Regulation (EC) No 648/2004 is amended in accordance with the following regulations.

5.—(1) Article 1 is amended as follows.

(2) For paragraph 1, substitute—

“1. This Regulation establishes technical standards and requirements in relation to detergents and surfactants for detergents designed to achieve the free movement of those products throughout the United Kingdom while, at the same time, ensuring a high degree of protection for human health and the environment.”

(3) In paragraph 2—

- (a) for the words before the first indent, substitute “For those purposes, this Regulation establishes rules including those concerning the following aspects of placing detergents and surfactants for detergents on the market.”;
- (b) in the fourth indent, for “Member States’ competent authorities”, substitute “competent authority”.

6.—(1) Article 2 is amended as follows.

(2) In paragraph 9—

- (a) omit “Union” in the first place it appears;
- (b) for “Union customs territory”, substitute “United Kingdom”.

(3) In paragraph 9a, for “Union”, substitute “United Kingdom”.

(4) In paragraph 10, after “natural or legal”, insert “established in the United Kingdom”.

(5) After paragraph 12, insert—

“13. ‘Competent authority’ means the Secretary of State.

14. ‘Regulation (EU) 528/2012’ means Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products.

15. ‘the REACH Regulation’ means Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency.”

7.—(1) Article 3 is amended as follows.

(2) In paragraph 1—

(a) in the words before point (a)—

- (i) in the first sentence, omit “and, where relevant, with Directive 98/8/EC and with any other relevant Community legislation”;
- (ii) in the second sentence, for “Directive 98/8/EC”, substitute “point (c) of Article 3(1) of Regulation (EU) 528/2012”;

(b) for point (a), substitute—

“(a) they are included in:

- the UK list of approved active substances referred to in Article 8A of Regulation (EU) 528/2012, or

(a) See Decision Nos 144/2005, 15/2007, 66/2010, 106/2012 and 140/2013 of the EEA Joint Committee and point 12u in Chapter 15 of Annex 2 to the EEA agreement available at www.efta.int/eea-lex.

- the Simplified Active Substance List referred to in Article 24A of Regulation (EU) 528/2012(a).”;
 - (c) in point (b), for “Article 15(1) or 15(2) of Directive 98/8/EC”, substitute “Article 55(1) or (2) of Regulation (EU) 528/2012”;
 - (d) in point (c), for “or subject to the 10 year work programme provided for in Article 16 of Directive 98/8/EC”, substitute “provided for in Article 89(2) of Regulation (EU) 528/2012”.
- (3) Omit paragraph 2.
- 8.**—(1) Article 5 is amended as follows.
- (2) In paragraph 1—
- (a) in the first sentence, omit “of the Member State concerned, referred to in Article 8(1), and to the Commission,”;
 - (b) in the second sentence—
 - (i) for “Member States”, substitute “The competent authority”;
 - (ii) omit “to the Member State’s competent authority”.
- (3) In paragraph 2, in the third subparagraph—
- (a) in the first sentence, for “a tiered approach”, substitute “the tiered approach referred to in the Commission Recommendation of 23rd December 2005 on the tiered approach technical guidance document for the purpose of implementing Regulation (EC) No 648/2004 of the European Parliament and the Council”;
 - (b) omit the second and third sentences.
- (4) In paragraph 3—
- (a) in the first subparagraph—
 - (i) omit “of the Member State”;
 - (ii) for the comma after “requests”, substitute “and”;
 - (iii) omit “and inform the Commission about the results”;
 - (b) in the second subparagraph—
 - (i) omit “of the Member State” in both places it occurs;
 - (ii) omit the final sentence.
- (5) In paragraph 4—
- (a) in the first sentence—
 - (i) for “by the Member State, the Commission”, substitute “under paragraph 3, the competent authority”;
 - (ii) omit “in accordance with the procedure referred to in Article 12(2)”;
 - (b) omit the second sentence;
 - (c) for the third sentence, substitute “The competent authority shall make its decision within 12 months of completing the evaluation carried out under paragraph 3.”.
- (6) In paragraphs 5 and 6, for “Commission” in each place it occurs, substitute “competent authority”.
- 9.**—(1) Article 6 is amended as follows.
- (2) In paragraph 1—
- (a) in the words before the first indent—
 - (i) for “Commission”, substitute “competent authority”;

(a) Further explanation is available on the website of the Health and Safety Executive (www.hse.gov.uk/biocides).

- (ii) omit “in accordance with the procedure referred to in Article 12(2), and”;
 - (b) in the third indent, for “Community”, substitute “United Kingdom”.
- (3) Omit paragraphs 2 and 3.
- (4) In paragraph 4—
- (a) for “Commission”, substitute “competent authority”;
 - (b) for “in Annex VI the”, substitute “a”.

10.—(1) Article 7 is amended as follows.

(2) In the first sentence, for “Article 10(5) of Regulation (EEC) No 793/93”, substitute “Article 13(4) of the REACH Regulation”.

(3) In the fourth sentence—

- (i) omit “or the Member State”;
- (ii) for “Commission”, substitute “Secretary of State”.

(4) Omit the fifth sentence.

(5) At the end, insert the following paragraphs—

“For each case submitted, the Secretary of State must make a decision as to whether or not the relevant tests may be accepted. The Secretary of State must:

- make a decision within 90 days of receiving the manufacturer’s submission;
- take appropriate expert advice and take that advice into account when coming to a decision;
- after taking a decision, promptly communicate it to the manufacturer concerned together with an explanation of the appeal process set out below.

If the Secretary of State decides that the relevant tests may not be accepted, the manufacturer may, within 14 days of having that decision communicated to it by the Secretary of State, appeal to the court against that decision.

On appeal, the court may—

- allow the appeal and rule that the tests may be accepted,
- allow the appeal but rule that the tests may only be accepted if conditions specified by the court are fulfilled, or
- dismiss the appeal.

(Article 18A makes further provision concerning appeals).”.

11.—(1) Article 8 is amended as follows.

(2) For the heading, substitute—

“Approved laboratories”.

(3) Omit paragraph 1.

(4) For paragraph 2, substitute—

- “2. Tests required by this Regulation may be carried out by approved laboratories only.
- ‘Approved laboratories’ are laboratories that are:
- members of the UK GLP compliance programme referred to in the Good Laboratory Practice Regulations 1999 (a), or

(a) S.I. 1999/3106.

- able to demonstrate compliance with standard EN ISO/IEC 17025: 2017 (general requirements for the competence of testing and calibration laboratories)(a) to the satisfaction of the competent authority.”.

(5) Omit paragraph 3.

(6) For paragraph 4, substitute—

“(4) The competent authority shall publish a list of approved laboratories.”.

12.—(1) Article 9 is amended as follows.

(2) In paragraph 1, in the words before the first indent, for “authorities of the Member States”, substitute “authority”.

(3) In paragraph 2, in the second sentence—

(a) for “He”, substitute “The manufacturer”;

(b) for “he”, substitute “the manufacturer”.

(4) In paragraph 3—

(a) in the second subparagraph—

(i) for “a Member State”, substitute “the relevant Ministers”;

(ii) for “a specific public body to which the Member State has assigned”, substitute “the National Poisons Information Service (‘NPIS’) or such other body to which the relevant Ministers assign”;

(iii) at the end, insert “within their respective territories”;

(b) after the second subparagraph, insert—

“For the purposes of this Article, ‘the relevant Ministers’ means:

— in England, the Secretary of State;

— in Wales, the Welsh Ministers;

— in Scotland, the Scottish Ministers;

— in Northern Ireland, the Department of Agriculture, Environment and Rural Affairs;

(c) in the third subparagraph, for “specific public body”, substitute “the NPIS or other body assigned under the second subparagraph”.”

13.—(1) Article 10 is amended as follows.

(2) In paragraph 1, for “Member States’ competent authorities”, substitute “The competent authority”.

(3) In paragraph 2, for the words from “the Member States” to “necessary measures.”, substitute “the competent authority must make a decision as to whether or not the test concerned produced a false positive result. The competent authority must:

— make a decision within 90 days of it becoming aware of a concern that the relevant test may have produced a false positive result;

— take appropriate expert advice and take that advice into account when coming to a decision;

— after taking a decision, promptly communicate it to the manufacturer concerned together with an explanation of the appeal process set out below.”.

(4) After paragraph 2, insert—

“3. If the competent authority decides that a test produced false positive results:

— those results must be disregarded for the purpose of ensuring compliance with the provisions of this Regulation;

(a) A copy of standard EN ISO/IEC 17025: 2017 may be obtained from the British Standards Institution, either online (www.bsigroup.com) or by post (BSI Customer Services, 389 Chiswick High Road, London, W4 4AL).

— the manufacturer may, within 14 days of having that decision communicated to it by the competent authority, appeal to the court against the decision.

4. On appeal, the court may:

- allow the appeal and rule that the tests did not produce false positive results, or
- dismiss the appeal.

(Article 18A makes further provision concerning appeals).”.

14.—(1) Article 11 is amended as follows.

(2) For paragraph 5, substitute—

“5. The information specified in paragraphs 3 and 4 must be in English although this does not prevent the same information from also appearing in other languages.”.

(3) Omit paragraph 6.

15. Omit Article 12.

16. For Article 13, substitute—

“Article 13

Power to amend the Annexes

1. The Secretary of State may make regulations:

- amending Annexes 1 to 4, 7 and 8 to this Regulation for the purpose of adapting them to scientific and technical progress;
- amending the provisions of the Annexes to this Regulation that concern solvent-based detergents;
- amending the concentration levels of allergenic fragrances set out in section A of Annex 7 to this Regulation to reflect individual risk-based concentration limits for fragrance allergens established by the Scientific Committee on Consumer Safety referred to in Article 1 of Commission Decision 721/2008 setting up an advisory structure of Scientific Committees and experts in the field of consumer safety, public health and the environment.

2. Regulations made under the first indent in paragraph 1 shall, wherever possible, reflect international standards.

3. Regulations under this Article may make:

- consequential, supplementary, incidental, transitional, transitory or saving provision;
- different provision for different purposes.

4. Regulations under this Article are to be made by statutory instrument.

5. A statutory instrument containing regulations under this Article is subject to annulment in pursuance of a resolution of either House of Parliament.”.

17. Omit Articles 13a and 14.

18. Omit Article 16.

19. In Article 17, omit paragraph 4.

20. Omit Article 18.

21. Before Article 19, insert—

“Article 18A

Appeals

1. In this Regulation, “court” means:

- in England and Wales, the county court;
 - in Scotland, the sheriff;
 - in Northern Ireland, a county court.
2. Despite any rule of court to the contrary, an appeal under this Regulation:
- is to be a rehearing of the relevant decision;
 - may be determined having regard to matters of which the competent authority or Secretary of State was unaware when making the decision.
3. The following courts may transfer appeal proceedings under this Regulation to the High Court:
- in England and Wales, the county court;
 - in Northern Ireland, a county court.
4. In Scotland, the sheriff may transfer appeal proceedings under this Regulation to the Court of Session.”.

22. After Article 19, omit the words “This Regulation shall be binding in its entirety and directly applicable in all Member States.”.

23.—(1) Annex 1 is amended as follows.

(2) In paragraph 1—

- (a) for “EN ISO/IEC 17025”, substitute “EN ISO/IEC 17025: 2017”;
- (b) for “Directive 2004/10/EC”, substitute “The Good Laboratory Practice Regulations 1999”;
- (c) for “Council Directive 86/609/EEC”, substitute “The Animals (Scientific Procedures) Act 1986”(a).

(3) In paragraph 2—

- (a) for “EN 45003, Calibration and testing laboratory accreditation system, general requirements for operation and recognition”, substitute “BS EN ISO/IEC 17011: 2017. Conformity Assessment. Requirements for accreditation bodies accrediting conformity assessment bodies.”(b);
- (b) in the second subparagraph, for “Directive 2004/9/EC”, substitute “The Good Laboratory Practice Regulations 1999”.

24.—(1) Annex 2 is amended as follows.

(2) In sections A, B and D, for “competent authorities of the Member States”, in each place it occurs, substitute “competent authority”.

(3) In section C, for “competent national authorities of the Member States”, substitute “competent authority”.

25.—(1) Annex 3 is amended as follows.

(2) In Part A—

- (a) for paragraph 2, substitute “Council Regulation (EC) No 440/2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (“EU Regulation 440/2008”), Annex, Part C: Methods for the determination of ecotoxicity, Part 4 (CO₂ (carbon dioxide) evolution test (method C.4-C)).”;

(a) 1986 c. 14.

(b) A copy of standard BS EN ISO/IEC 17011: 2017 may be obtained from the British Standards Institution, either online (www.bsigroup.com) or by post (BSI Customer Services, 389 Chiswick High Road, London, W4 4AL).

- (b) for paragraph 3, substitute “EU Regulation 440/2008, Annex, Part C: Methods for the determination of ecotoxicity, Part 6 (closed bottle test (method C.4-E)).”;
- (c) for paragraph 4, substitute “EU Regulation 440/2008, Annex, Part C: Methods for the determination of ecotoxicity, Part 5 (manometric respirometry test (method C.4-D)).”;
- (d) for paragraph 5, substitute “EU Regulation 440/2008, Annex, Part C: Methods for the determination of ecotoxicity, Part 7 (M.I.T.I. test (method C.4-F)).”.

(3) In Part B—

- (a) for paragraph 1, substitute “EU Regulation 440/2008, Annex, Part C: Methods for the determination of ecotoxicity, Part 2 (DOC die-away test (method C.4-A)).”;
- (b) for paragraph 2, substitute, “EU Regulation 440/2008, Annex, Part C: Methods for the determination of ecotoxicity, Part 3 (modified OECD screening test (method C.4-B)).”;
- (c) omit the final, unnumbered paragraph that begins “NB”.

26.—(1) Annex 4 is amended as follows.

(2) In the first paragraph, for “Directive 93/67/EEC, or Regulation (EEC) No 793/93 and Regulation (EC) No 1488/94”, substitute “the REACH Regulation”.

(3) In the second paragraph, for “Directive 93/67/EEC, or Regulation (EEC) No 793/93”, substitute “the REACH Regulation”.

(4) In the third paragraph, for “Committee referred to in Article 12(2)”, substitute “competent authority”.

(5) In the fourth paragraph, for the second sentence, substitute—

“If the manufacturer disputes the competent authority’s view concerning the extent of the additional information required, it may submit the case to the Secretary of State for a decision. The Secretary of State must:

- within 90 days of the manufacturer submitting the case, make a decision as to the extent of additional information required;
- take appropriate expert advice and take that advice into account when coming to a decision;
- after taking a decision, promptly communicate it to the manufacturer and the competent authority.”.

(6) Omit the fifth paragraph.

(7) In point 1, in the heading, omit “(in accordance with the provisions laid down by Annex VII.A of Directive 67/548/EEC)”.

(8) In point 3—

- (a) omit the second and third sentences;
- (b) at the end, insert the following paragraphs—

“If no data are available on residue identity then, depending on the potential risk and the importance and quantity of the surfactant used in detergents, the competent authority may require the manufacturer to provide it with the information referred to in point 4.2.1.

If the competent authority requires the manufacturer to provide that information and the manufacturer takes the view that the provision of that information is unnecessary, it may submit the case to the Secretary of State for a decision. The Secretary of State must:

- within 90 days of the manufacturer submitting the case, make a decision as to whether or not the provision of the information is necessary;
- take appropriate expert advice and take that advice into account when coming to a decision;
- after taking a decision, promptly communicate it to the manufacturer.”.

(9) In point 4.1.2—

- (a) for the first indent, substitute—
 - “— method of EU Regulation 440/2008, Annex, Part C, C.12. (biodegradation – modified SCAS test).”;
 - (b) for the second indent, substitute—
 - “— method of EU Regulation 440/2008, Annex, Part C, C.9. (biodegradation – Zahn-Wellens test).”.
- (10) In point 4.1.3, for the indent, substitute—
- “— method of EU Regulation 440/2008, Annex, Part C, C.10. (biodegradation – activated sludge simulation tests).”.
- (11) In point 4.2.2—
- (a) in the paragraph beginning with “Fish:”, for “Annex V.C.1 of Directive 67/548/EEC”, substitute “EU Regulation 440/2008, Annex, Part C, C.1. (acute toxicity for fish)”;
 - (b) in the paragraph beginning with “Daphnia:”, for “Annex V.C.2 of Directive 67/548/EEC”, substitute “EU Regulation 440/2008, Annex, Part C, C.2. (daphnia SP. acute immobilisation test)”;
 - (c) in the paragraph beginning with “Algae:”, for “Annex V.C.3 of Directive 67/548/EEC”, substitute “EU Regulation 440/2008, Annex, Part C, C.3. (algal inhibition test)”;
 - (d) in the paragraph beginning with “Bacteria:”, for “Annex V.C.11 of Directive 67/548/EEC”, substitute “EU Regulation 440/2008, Annex, Part C, C.11. (biodegradation – activated sludge respiration inhibition)”.
- (12) In point 4.2.3—
- (a) in the first paragraph, for “Annex V.C.5 of Directive 67/548/EEC”, substitute “EU Regulation 440/2008, Annex, Part C, C.5. (degradation – biochemical oxygen demand)”;
 - (b) in the second paragraph, for “Annex V.C.7 of Directive 67/548/EEC”, substitute “EU Regulation 440/2008, Annex, Part C, C.7. (degradation – abiotic degradation: hydrolysis as a function of PH)”.
- (13) Omit the final, unnumbered paragraph that begins “NB”.
- 27.** In Annex 5, in the first paragraph, omit “and in accordance with the procedure laid down in Article 12(2)”.
- 28.**—(1) Annex 7 is amended as follows.
- (2) In Part A—
- (a) in the fourth paragraph—
 - (i) for “nomenclature”, substitute “ingredient names”;
 - (ii) for the words from “Article 8” to “cosmetic products (recast)”, substitute “Article 33 of Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (“EU Regulation 1223/2009”)”;
 - (b) in the fifth paragraph—
 - (i) for the words from “substances in Annex III” to “the Council”, substitute “substances in Annex 3 to EU Regulation 1223/2009”;
 - (ii) for the words from “using the nomenclature” to the end, substitute “using (where possible) the common ingredient names established under Article 33 of EU Regulation 1223/2009”.
- (3) In Part B, in the paragraph after the third indent—
- (a) in the first sentence, for the words from “of Commission Decision 1999/476/EC” to the end, substitute “in Commission Decision (EU) 2017/1218 establishing the EU Ecolabel criteria for laundry detergents”;
 - (b) in the second sentence, after “heavy-duty detergent”, insert “(as defined in point (2) of Article 2(1) of that Decision)”.

(4) In Part C, in the definition of ‘Ingredient’, for “Annex III, Part 1 to Directive 76/768/EEC”, substitute “Annex 3 to EU Regulation 1223/2009”.

(5) In Part D, in the third indent, for “Annex III, Part 1 to Directive 76/768/EEC”, substitute “Annex 3 to EU Regulation 1223/2009”.

29. In Annex 8, in the first paragraph, for “carried out by Member States”, substitute “applied by the competent authority”.

	<i>Name</i>
	Parliamentary Under Secretary of State
Date	Department for Environment, Food and Rural Affairs

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations are made in exercise of the powers conferred by section 8(1) of the European Union (Withdrawal) Act 2018 (c. 16) (“the 2018 Act”) in order to address failures of retained EU law relating to detergents to operate effectively and other deficiencies (including those set out in paragraphs (a), (b), (c), (d) and (g) of section 8(2) of the 2018 Act which apply to this instrument) arising from the withdrawal of the UK from the European Union. They also restate retained EU law in a clearer and more accessible way (see paragraph 21 of Schedule 7 to the 2018 Act).

Part 2 amends EU-derived domestic legislation (the Detergents Regulations 2010 (S.I. 2010/740)).

Part 3 amends direct EU legislation (Regulation (EC) No 648/2004 (OJ No L104, 8.4.2004, p.1) and the corresponding legislation adopted under the EEA agreement).

Regulation (EC) No 648/2004 and the EEA agreement are published by the National Archives (National Archives, Kew, Richmond, Surrey, TW9 4DU) and are available on www.legislation.gov.uk.

An impact assessment has not been produced for this instrument as no, or no significant impact on the private or voluntary sector is foreseen.

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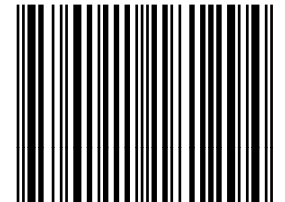
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