

REACH: Restrictions imposed on the Use of Phthalates in Plasticised Materials

Introduction

Recently, the Commission Regulation (EU) 2018/2005 ('Regulations') came into force imposing **restrictions on the use of four phthalates** namely bis(2-ethylhexyl) phthalate ('DEHP'), dibutyl phthalate ('DBP'), benzyl butyl phthalate ('BBP') and diisobutyl phthalate ('DIBP') (collectively referred to as 'phthalate') in Plasticised Materials.

The Regulations amend **Entry 51 of Annex XVII to Regulation (EC) No 1907/2006** in connection with the Registration, Evaluation, Authorisation and Restriction of Chemicals ('Reach Regulation') with regard to the phthalate.

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard 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 ⁽¹⁾, and in particular Article 68(1) thereof,

Whereas:

(1) Bis(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), benzyl butyl phthalate (BBP) and diisobutyl phthalate (DIBP) ('the four phthalates') are listed in Annex XIV to Regulation (EC) No 1907/2006 as substances toxic for reproduction, category 1B, with a sunset date of 21 February 2015, specified in accordance with Article 58(1)(c)(i) of that Regulation.

(2) After the sunset date referred to in Article 58(1)(c)(i) for a substance listed in Annex XIV, Article 69(2) of Regulation (EC) No 1907/2006 requires the European Chemicals Agency ('the Agency') to consider whether the use in articles of substances listed in Annex XIV to that Regulation poses a risk to human health or the environment that is not adequately controlled and, if the Agency considers that it does, to prepare a dossier for a restriction proposal which conforms to the requirements of Annex XV to Regulation (EC) No 1907/2006 ('the Annex XV dossier').

Entry 51 of Reach Regulation

Prior to the Regulations coming into force, Entry 51 of Reach Regulation was concerned with **phthalates used as substances or in mixtures, in concentrations greater than 0.1 % by**

weight of the plasticised material, in toys and childcare articles:

51. The following phthalates (or other CAS and EC numbers covering the substance): (a) Bis (2-ethylhexyl) phthalate (DEHP) CAS No 117-81-7 EC No 204-211-0 (b) Dibutyl phthalate (DBP) CAS No 84-74-2 EC No 201-557-4 (c) Benzyl butyl phthalate (BBP) CAS No 85-68-7 EC No 201-622-7	1. Shall not be used as substances or in mixtures, in concentrations greater than 0,1 % by weight of the plasticised material, in toys and childcare articles. 2. Toys and childcare articles containing these phthalates in a concentration greater than 0,1 % by weight of the plasticised material shall not be placed on the market. 3. The Commission shall re-evaluate, by 16 January 2010, the measures provided for in relation to this entry in the light of new scientific information on such substances and their substitutes, and if justified, these measures shall be modified accordingly. 4. For the purpose of this entry 'childcare article' shall mean any product intended to facilitate sleep, relaxation, hygiene, the feeding of children or sucking on the part of children.
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In 2011, DEHP was classified as **toxic** and included in Annex XIV to the Reach Regulation in accordance with Recital 7 of COMMISSION REGULATION (EU) No 143/2011. This meant that restrictions had to be **imposed on the use and the placing on the market of these phthalates** entered in Entry 51 of Reach Regulation:

(7) Bis(2-ethylhexyl) phthalate (DEHP) meets the criteria for classification as toxic for reproduction (category 1B) in accordance with Regulation (EC) No 1272/2008 and therefore meets the criteria for inclusion in Annex XIV to Regulation (EC) No 1907/2006 pursuant to Article 57(c) of that Regulation. It has been identified and included in the candidate list in accordance with Article 59 of that Regulation. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32011R0143>

A date had to be set from which the use and the placing on the market of DEHP would be prohibited in order to comply with Article 58(1)(c)(i) of the Reach Regulation In accordance with Recitals 12 and 13 of COMMISSION REGULATION (EU) No 143/2011, once DEHP was included in Annex XIV:

(12) For each substance listed in Annex XIV to Regulation (EC) No 1907/2006, where the applicant wishes to continue to use the substance or place the substance on the market, it is appropriate to set a date by which applications must be received by the European Chemicals Agency, in accordance with Article 58(1)(c)(ii) of that Regulation.

(13) For each substance listed in Annex XIV to Regulation (EC) No 1907/2006 it is appropriate to set a date from which the use and placing on the market is prohibited, in accordance with Article 58(1)(c)(i) of that Regulation.

...15)In accordance with Article 58(1)(c)(ii) of Regulation (EC) No 1907/2006, the latest application date is to be set at least 18 months before the sunset date.

(16) Article 58(1)(e) in conjunction with Article 58(2) of Regulation (EC) No 1907/2006 provides for the possibility of exemptions of uses or categories of uses in cases where there is specific Community legislation imposing minimum requirements relating to the protection of human health or the environment that ensures proper control of the risks.

Article 58

Inclusion of substances in Annex XIV

1. Whenever a decision is taken to include in Annex XIV substances referred to in Article 57, such a decision shall be taken in accordance with the procedure referred to in Article 133(4). It shall 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;

(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.

Entry 51 of Annex XVII Reach Regulation is repealed and replaced by the Annex to the Regulations. The Regulations **expanded the number of restricted phthalates** from three (DEHP, DBP and BBP) to four (DEHP, DBP, BBP and DIBP).

According to Recital 5 to the Regulations, the intention was to restrict the placing on the market of articles containing the **four phthalates** in a concentration **equal to or greater than 0.1 % by weight individually or in any combination in such plasticised materials** and exemptions for articles already placed on the market in the Union:

(5) The Annex XV dossier proposed to restrict the placing on the market of articles containing the four phthalates in a concentration equal to or greater than 0,1 % by weight individually or in any combination in such plasticised materials. This concentration limit would effectively discourage the use of the four phthalates in articles within the scope of the restriction. The dossier suggested exemptions for articles exclusively for open air use without prolonged contact with skin or contact with mucous membranes, certain articles exclusively for industrial and agricultural use, measuring devices, articles covered by existing Union legislation and

Paragraphs 1 and 2 of the Annex to the Regulations are concerned with the restrictions in **Entry 51 of Annex XVII Reach Regulation** in relation to the use and the placing on the market of the four phthalates in relation to **toys and childcare articles**.

Exemptions

There are a number of exemptions:

The proposed restriction should also not apply to measuring devices for laboratory use or articles that form part of such devices and to articles placed on the market prior to the date of entry into application of the restriction, for practicality and enforceability reasons. Moreover, certain derogations should apply for motor vehicles and aircraft. First, a longer deferral of application of the restriction for motor vehicles and an indefinite exemption for articles used in the maintenance or repair of those vehicles, where the vehicles cannot function as intended without those articles, are justified in consideration of the specific economic implications of this sector. A longer deferral of application of the restriction for certain aircraft and an indefinite exemption for articles used in the maintenance or repair of those aircraft where these are essential for safety and airworthiness, are justified on the basis that aircrafts have a very long useful life, their airworthiness may be jeopardised if parts meeting the design specifications are not available and the timelines needed for requalification are very long.

(16) Taking into account the Annex XV dossier as well as the opinions of RAC and SEAC, the Commission considers that the proposed restriction would address the identified risks without imposing significant burden on industry, supply chain or consumers and concludes that the restriction proposed, is an appropriate Union-wide measure to address the identified risk.

(17) Stakeholders should be allowed sufficient time to take appropriate measures to comply with the proposed restriction and 18 months is sufficient to this end. Therefore there should be a general deferral of its application by 18 months. A longer specific deferral of 60 months should apply to address the particular cases of certain motor vehicles and aircraft.

A copy of the Annex is reproduced below:

ANNEX

Entry 51 of Annex XVII to Regulation (EC) No 1907/2006 is replaced by the following:

<p>51.</p> <p>Bis(2-ethylhexyl) phthalate (DEHP)</p> <p>CAS No.: 117-81-7</p> <p>EC No.: 204-211-0</p> <p>Dibutyl phthalate (DBP)</p> <p>CAS No.: 84-74-2</p> <p>EC No.: 201-557-4</p> <p>Benzyl butyl phthalate (BBP)</p> <p>CAS No.: 85-68-7</p> <p>EC No.: 201-622-7</p> <p>Diisobutyl phthalate (DIBP)</p> <p>CAS No.: 84-69-5</p> <p>EC No.: 201-553-2</p>	<ol style="list-style-type: none"> 1. Shall not be used as substances or in mixtures, individually or in any combination of the phthalates listed in column 1 of this entry, in a concentration equal to or greater than 0,1 % by weight of the plasticised material, in toys and childcare articles. 2. Shall not be placed on the market in toys or childcare articles, individually or in any combination of the first three phthalates listed in column 1 of this entry, in a concentration equal to or greater than 0,1 % by weight of the plasticised material. In addition, DIBP shall not be placed on the market after 7 July 2020 in toys or childcare articles, individually or in any combination with the first three phthalates listed in column 1 of this entry, in a concentration equal to or greater than 0,1 % by weight of the plasticised material. 3. Shall not be placed on the market after 7 July 2020 in articles, individually or in any combination of the phthalates listed in column 1 of this entry, in a concentration equal to or greater than 0,1 % by weight of the plasticised material in the article. 4. Paragraph 3 shall not apply to: <ol style="list-style-type: none"> (a) articles exclusively for industrial or agricultural use, or for use exclusively in the open air, provided that no plasticised material comes into contact with human mucous membranes or into prolonged contact with human skin; (b) aircraft, placed on the market before 7 January 2024, or articles, whenever placed on the market, for use exclusively in the maintenance or repair of those aircraft, where those articles are essential for the safety and airworthiness of the aircraft; (c) motor vehicles within the scope of Directive 2007/46/EC, placed on the market before 7 January 2024, or articles, whenever placed on the market, for use exclusively in the maintenance or repair of those vehicles, where the vehicles cannot function as intended without those articles; (d) articles placed on the market before 7 July 2020; (e) measuring devices for laboratory use, or parts thereof; (f) materials and articles intended to come into contact with food within the scope of Regulation (EC) No 1935/2004 or Commission Regulation (EU) No 10/2011 (*); (g) medical devices within the scope of Directives 90/385/EEC, 93/42/EEC or 98/79/EC, or parts thereof; (h) electrical and electronic equipment within the scope of Directive 2011/65/EU; (i) the immediate packaging of medicinal products within the scope of Regulation (EC) No 726/2004, Directive 2001/82/EC or Directive 2001/83/EC; (j) toys and childcare articles covered by paragraphs 1 or 2.
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	<p>5. For the purposes of paragraphs 1, 2, 3 and 4(a),</p> <p>(a) 'plasticised material' means any of the following homogeneous materials:</p> <ul style="list-style-type: none"> — polyvinyl chloride (PVC), polyvinylidene chloride (PVDC), polyvinyl acetate (PVA), polyurethanes, — any other polymer (including, inter alia, polymer foams and rubber material) except silicone rubber and natural latex coatings, — surface coatings, non-slip coatings, finishes, decals, printed designs, — adhesives, sealants, paints and inks. <p>(b) 'prolonged contact with human skin' means continuous contact of more than 10 minutes duration or intermittent contact over a period of 30 minutes, per day.</p> <p>(c) 'childcare article' shall mean any product intended to facilitate sleep, relaxation, hygiene, the feeding of children or sucking on the part of children.</p> <p>6. For the purposes of paragraph 4(b), 'aircraft' means one of the following:</p> <p>(a) a civil aircraft produced in accordance with a type certificate issued under Regulation (EC) No 216/2008 or with a design approval issued under the national regulations of a contracting State of the International Civil Aviation Organisation (ICAO), or for which a certificate of airworthiness has been issued by an ICAO contracting State under Annex 8 to the Convention on International Civil Aviation, signed on December 7, 1944, in Chicago;</p> <p>(b) a military aircraft.</p>
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(*) Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food (OJ L 12, 15.1.2011, p. 1).

Paragraph 3 of the Annex to the Regulations, broadens the restrictions in Entry 51 of Annex XVII Reach Regulation **to plasticised material in the article**, not simply toys and childcare articles.

In accordance with the Annex to the Regulations, the restrictions in paragraph 3 apply if the concentration of DEHP is equal to or greater than 0.1 % by weight of the plasticised material in the Existing Articles.

Effective Dates

The entry into force of the restrictions is as follows:

Entry 51 of the Annex to the Regulations	Restriction in the Annex to the Regulations	Entry into force
	1... Used as substances or in mixtures in toys and childcare articles	7 January 2019 for DEHP, DBP, BBP and DIBP

	2... Placing toys and childcare articles on the market	7 January 2019 for DEHP, DBP and BBP
	3...Placing articles on the market	7 July, 2020 for DEHP, DBP, BBP and DIBP

Plasticised Materials

The restrictions apply to plasticised materials and according to Recital 11 of the Regulations and paragraph 5 of the Annex to the Regulations, **plasticised materials** are defined as:

11 ...For the purposes of this restriction, plasticised materials are materials that may contain phthalates for which there is great potential for combined exposure, via various routes, of both consumers and workers. Those materials include polyvinyl chloride (PVC), polyvinylidene chloride (PVDC), polyvinyl acetate (PVA), polyurethanes, any other polymer (including, inter alia, polymer foams and rubber material) except silicone rubber and natural latex coatings, surface coatings, non-slip coatings, finishes, decals, printed designs, adhesive, sealants, inks and paints. The Commission considers that the risk needs to be addressed on a Union-wide basis.

5 For the purposes of paragraphs 1, 2, 3 and 4(a), 'plasticised material' means any of the following homogeneous materials: polyvinyl chloride (PVC), polyvinylidene chloride (PVDC), polyvinyl acetate (PVA), polyurethanes, any other polymer (including, inter alia, polymer foams and rubber material) except silicone rubber and natural latex coatings, surface coatings, non-slip coatings, finishes, decals, printed designs, adhesives, sealants, paints and inks...

Enforcement

The Health and Safety Executive ('HSE') has the responsibility to enforce the REACH Regulation in England.

Please visit our website [here](#) or you may contact us by email enquiries@rtcooperssolicitors.com.

Contact us.

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