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European Union

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| To: | General Secretariat of the Council |

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| Subject: | ANNEX to the COMMISSION REGULATION (EU) .../... of XXX amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards bis(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), benzyl butyl phthalate (BBP) and diisobutyl phthalate (DIBP) |

Delegations will find attached document D057230/02.

Encl.: D057230/02



Brussels, XXX
D057230/02
[...] (2018) XXX draft

ANNEX 1

ANNEX

to the

**COMMISSION REGULATION (EU) .../...
of XXX**

amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards bis(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), benzyl butyl phthalate (BBP) and diisobutyl phthalate (DIBP)

ANNEX

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

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| <p>“51.</p> <p>Bis(2-ethylhexyl) phthalate (DEHP) CAS No.: 117-81-7 EC No.: 204-211-0</p> <p>Dibutyl phthalate (DBP) CAS No.: 84-74-2 EC No.: 201-557-4</p> <p>Benzyl butyl phthalate (BBP) CAS No.: 85-68-7 EC No.: 201-622-7</p> <p>Diisobutyl phthalate (DIBP) CAS No.: 84-69-5 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. <p>In addition, DIBP shall not be placed on the market after <i>[OJ please insert date: 18 months after the date of entry into force]</i> 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.</p> <ol style="list-style-type: none">3. Shall not be placed on the market after <i>[OJ please insert date: 18 months after the date of entry into force]</i> 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 <i>[OJ please insert date – 60 months after the date of entry into force]</i>, or articles, whenever placed on the market, for use exclusively in |
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| | <p>the maintenance or repair of those aircraft, where those articles are essential for the safety and airworthiness of the aircraft;</p> <p>(c) motor vehicles within the scope of Directive 2007/46/EC, placed on the market before <i>[OJ please insert date – 60 months after the date of entry into force]</i>, 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;</p> <p>(d) articles placed on the market before <i>[OJ please insert date: 18 months after the date of entry into force]</i>;</p> <p>(e) measuring devices for laboratory use, or parts thereof;</p> <p>(f) materials and articles intended to come into contact with food within the scope of Regulation (EC) No 1935/2004 or Commission Regulation (EC) No 10/2011(*);</p> <p>(g) medical devices within the scope of Directives 90/385/EEC, 93/42/EEC or 98/79/EC, or parts thereof;</p> <p>(h) electrical and electronic equipment within the scope of Directive 2011/65/EU;</p> <p>(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;</p> <p>(j) toys and childcare articles covered by paragraphs 1 or 2.</p> <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. |
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| | <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 (EU) 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).”