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TEXTS ADOPTED

*Provisional edition*

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**P8\_TA-PROV(2015)0409**

**Authorisation for uses of bis(2-ethylhexhyl) phthalate (DEHP)**

**European Parliament resolution of 25 November 2015 on draft Commission Implementing Decision XXX granting an authorisation for uses of bis(2-ethylhexhyl) phthalate (DEHP) under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (D041427 – 2015/2962(RSP))**

*The European Parliament,*

- having regard to the draft Commission implementing decision granting an authorisation for uses of bis(2-ethylhexhyl) phthalate (DEHP) under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (D041427),
- having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council<sup>1</sup>, in particular Article 64(8) thereof,
- having regard to the opinions of the Committee for Risk Assessment (RAC) and the Committee for Socio-Economic Analysis (SEAC)<sup>2</sup>, pursuant to the third subparagraph of Article 64(5) of Regulation (EC) No 1907/2006,
- having regard to Article 11 of Regulation (EU) No 182/2011 of the European Parliament and of the Council<sup>3</sup>,
- having regard to Directive 2008/98/EC<sup>1</sup>, in particular Article 4 thereof,

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<sup>1</sup> 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 (OJ L 396, 30.12.2006, p. 1).

<sup>2</sup> <http://echa.europa.eu/documents/10162/b50d9fc3-f6db-4e91-8a95-c8397bb424d2>  
<http://echa.europa.eu/documents/10162/8d9ee7ac-19cf-4b1a-ab1c-d8026b614d7a>

<sup>3</sup> Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

- having regard to Decision No 1386/2013/EU of the European Parliament and of the Council<sup>2</sup>, in particular paragraph 43(viii) of the Annex thereto,
  - having regard to Commission Delegated Directive (EU) 2015/863<sup>3</sup>,
  - having regard to its resolution of 9 July 2015 on resource efficiency: moving towards a circular economy<sup>4</sup>,
  - having regard to the motion for a resolution by its Committee on the Environment, Public Health and Food Safety,
  - having regard to Rule 106(2) and (3) of its Rules of Procedure,
- A. whereas DEHP is included in Annex XIV to Regulation (EC) No 1907/2006 (the REACH Regulation) because of its classification as a category 1B substance that is toxic to reproduction; whereas DEHP is on the REACH candidate list because of its reprotoxic properties;
- B. whereas the Commission is aiming, through a draft implementing decision on the identification of bis(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), benzyl butyl phthalate (BBP) and diisobutyl phthalate (DIBP) as substances of very high concern according to Article 57(f) of Regulation (EC) No 1907/2006 of the European Parliament and of the Council, to identify DEHP as a substance of very high concern;
- C. whereas already in 2000, on the basis of the Communication from the Commission to the Council and the European Parliament on a Community Strategy for Endocrine Disrupters (COM(1999)0706), DEHP was included in Annex 1 setting out the candidate list of 553 substances under category I of chemicals that showed evidence of endocrine disrupting activity in at least one species using intact animals<sup>5</sup>;
- D. whereas DEHP was among the first six compounds due to be phased out under the REACH Regulation, as announced by the Commission on 17 February 2011<sup>6</sup>;
- E. whereas, on 12 December 2014, the Member State Committee (MSC) unanimously agreed to the identification of DEHP as a substance giving rise to an equivalent level of concern due to its endocrine disrupting properties in the environment<sup>7</sup>; whereas the MSC unanimously acknowledged that, in the case of DEHP, there is scientific evidence

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<sup>1</sup> Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives (OJ L 312, 22.11.2008, p. 3).

<sup>2</sup> Decision No 1386/2013/EU of the European Parliament and of the Council of 20 November 2013 on a General Union Environment Action Programme to 2020 ‘Living well, within the limits of our planet’ (OJ L 354, 28.12.2013, p. 171).

<sup>3</sup> Commission Delegated Directive (EU) 2015/863 of 31 March 2015 amending Annex II to Directive 2011/65/EU of the European Parliament and of the Council as regards the list of restricted substances (OJ L 137, 4.6.2015, p. 10).

<sup>4</sup> Texts adopted, P8\_TA(2015)0266.

<sup>5</sup> [http://ec.europa.eu/environment/archives/docum/pdf/bkh\\_annex\\_01.pdf](http://ec.europa.eu/environment/archives/docum/pdf/bkh_annex_01.pdf)

<sup>6</sup> [http://europa.eu/rapid/press-release\\_IP-11-196\\_en.htm?locale=en](http://europa.eu/rapid/press-release_IP-11-196_en.htm?locale=en)

<sup>7</sup> [http://echa.europa.eu/view-article/-/journal\\_content/title/the-member-state-committee-unanimously-agreed-to-identify-the-phthalate-dehp-as-an-svhc-because-of-its-endocrine-disrupting-properties-in-the-environm](http://echa.europa.eu/view-article/-/journal_content/title/the-member-state-committee-unanimously-agreed-to-identify-the-phthalate-dehp-as-an-svhc-because-of-its-endocrine-disrupting-properties-in-the-environm)

on endocrine disrupting activity and on the causal link between this activity and adverse effects on human health;

- F. whereas the Commission notes the unanimous agreement in the MSC on stating that four phthalates, including DEHP, have endocrine disrupting properties and that the adverse effects of this mode of action are the same as those which led to their classification as toxic to reproduction and their identification as substances of very high concern under Article 57(c) of the REACH Regulation; whereas the Commission also notes that the majority of members of the MSC considered that the level of concern to which those effects give rise is equivalent;
- G. whereas, on 21 October 2015, the Commission submitted a draft implementing act to identify DEHP as a substance having endocrine disrupting properties whose effects on human health give rise to an equivalent level of concern under Article 57(f) of the REACH Regulation;
- H. whereas the RAC opinion does acknowledge the endocrine mode of action of DEHP but also recognises that it has been included in Annex XIV because of its reproductive toxicity classification (Article 57(c)) and not on the basis of endocrine disrupting properties (Article 57(f)); whereas, as a consequence, the current assessment of DEHP is limited to its reproductive toxicity;
- I. whereas DEHP should be identified as a substance of very high concern because it meets the criteria set out in Article 57(f) of the REACH Regulation in that it is a substance with endocrine disrupting properties for which there is scientific evidence of probable serious effects on human health, which give rise to a level of concern equivalent to that for other substances listed in points (a) to (e) of Article 57 of the REACH Regulation;
- J. whereas the applicant has applied for authorisation through the adequate control route provided for in Article 60(2) of the REACH Regulation; whereas, however, under Article 60(3)(a) of the REACH Regulation, the adequate control route does not apply to substances meeting the criteria in the CMR classification or under Article 57(f) of that regulation for which it is not possible to determine a threshold in accordance with Section 6.4 of Annex I to the regulation;
- K. whereas DEHP has been shown to adversely affect the endocrine system of mammals primarily through in vivo findings on reduced foetal testosterone; whereas these findings are further substantiated by mechanistic findings, also in vivo, of down-regulation of genes in the steroidogenic biosynthesis pathway; whereas the spectrum of adverse effects observed in rats include increased nipple retention, decreased anogenital distance, genital malformations, a reduced number of spermatocytes and testicular changes including multinucleated gonocytes, tubular atrophy and Leydig cell hyperplasia;
- L. whereas scientific evidence on DEHP shows that exposure during sensitive time windows of development may cause irreversible developmental programming effects leading to severe effects on development and reproduction, regarded as particularly serious in relation to human health and wildlife species, also because these adverse effects may first manifest themselves in later life stages as a consequence of exposure during early life stages;

- M. whereas, according to the RAC opinion, based on the information provided in the applications, applicants did not demonstrate that the risks to workers' health from the uses applied for were adequately controlled in accordance with Article 60(2) of the REACH Regulation; whereas, according to the RAC, it is therefore not appropriate to grant the authorisation based on that provision;
- N. whereas, despite the RAC opinion, the Committee for Socio-Economic Analysis (SEAC) concluded that authorisation of the uses would be proportionate and thus that the socio-economic benefits arising from the uses covered by the application outweighed the risks to human health arising from those uses; whereas the SEAC opinion confirmed that there were significant deficiencies in the socio-economic analysis presented by the applicant, including the lack of any health impact assessment identifying the remaining risk to workers' health;
- O. whereas the SEAC is a scientific committee whose task, under Article 64(4)(b) of the REACH Regulation, is to assess socio-economic factors and the availability and technical feasibility of alternatives associated with use(s) of the substance as described in the application, and whereas its role is not to provide conclusions on the proportionality of an authorisation when the risk to society is not adequately controlled;
- P. whereas the applicant is responsible for assessing and managing the risks posed by chemicals and providing appropriate safety information to their users; whereas the SEAC could not conclude quantitatively on the proportionality of the continued use as information on the remaining risks to workers' health could not be quantified;
- Q. whereas the purpose of the REACH Regulation is to ensure a high level of protection of human health and the environment, including the promotion of alternative methods for assessment of the hazards posed by substances, and the free circulation of substances on the internal market, while enhancing competitiveness and innovation;
- R. whereas the applications concern a wide range of uses, which would include use in the formulation of recycled soft PVC containing DEHP in compounds and dry-blends and the industrial use of recycled soft PVC containing DEHP in polymer processing to produce PVC articles; whereas such a broad scope for authorisation would largely reverse the substitution of DEHP as intended by its inclusion in Annex XIV to the REACH Regulation;
- S. whereas DEHP in PVC is widely used in everyday consumer products such as textiles, furniture and building material; whereas it is not chemically bound to the plastic and thus easily leaches out to the environment;
- T. whereas an application for authorisation should focus on the use of the substance, and whereas the fact that the substance is present in recycled materials is not a relevant consideration for granting an authorisation;
- U. whereas the SEAC noted that it was possible to use post-industrial waste with low DEHP content as an alternative feedstock material, which would also increase the quality of the recyclates produced, but that it would be unlikely that the recycler would be able to pass on a price increase for better-quality recyclates to the downstream user, as they tend to produce articles that are at the lower end of the value spectrum; whereas the SEAC stated that the alternative for plastic converters of using virgin PVC with

other non-SVHC plasticisers as feedstock rather than recycled material was not considered, as the applicants indicated that the plastic converters might not remain competitive after incurring the additional cost of using virgin PVC;

- V. whereas it is not acceptable to tolerate potentially numerous cases of male infertility simply to allow soft PVC recyclers and downstream users to save costs in the production of low-value articles so as to compete with low-quality imports;
- W. whereas, although DEHP has a wide range of substitutes, the applicants have not provided a comprehensive analysis of alternatives available on the market to substitute the use of DEHP for the uses applied for;
- X. whereas one of the arguments given by the SEAC in favour of granting authorisation is that ‘there is a political and societal incentive to promote recycling as a sustainable way to handle natural resources’; whereas this simplistic argument disregards the waste management hierarchy laid down in Article 4 of Directive 2008/98/EC, according to which prevention takes priority over recycling; whereas this simplistic argument also fails to recognise explicit provisions in the Seventh Environment Action Programme which call for the development of non-toxic material cycles so that recycled waste can be used as a major, reliable source of raw material for the Union;
- Y. whereas, moreover, Parliament stressed in its resolution of 9 July 2015 on ‘resource efficiency: moving towards a circular economy’ that recycling should not justify the perpetuation of the use of hazardous legacy substances; whereas DEHP is a legacy substance, and has also been recognised as such by the industry concerned<sup>1</sup>;
- Z. whereas the use of DEHP has been restricted in electrical and electronic equipment pursuant to Commission Delegated Directive (EU) 2015/863; whereas this was supported inter alia by an assessment of the availability of safer alternatives for DEHP, as well as a positive socio-economic assessment<sup>2</sup>;
- AA. whereas the SEAC finds that it cannot conclude that there would be net societal costs, based on the information provided by the applicant, if authorisation was not granted; whereas, therefore, the applicants have not demonstrated the socio-economic benefits arising from the use of the substance and the socio-economic implications of a refusal to authorise as provided for in Article 60(4)(c) of the REACH Regulation;
- AB. whereas the granting of an authorisation for an application that is fraught with so many deficiencies would set a very bad precedent for future authorisation decisions under REACH;
- AC. whereas Article 1(3) of the REACH Regulation states that it is underpinned by the precautionary principle, and whereas, in the event of uncertainty, considerations relating to the protection of human health and the environment should prevail over general economic considerations;

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<sup>1</sup> [http://www.vinylplus.eu/uploads/docs/VinylPlus\\_Progress\\_Report\\_2015\\_English.pdf](http://www.vinylplus.eu/uploads/docs/VinylPlus_Progress_Report_2015_English.pdf)  
<sup>2</sup> [http://www.umweltbundesamt.at/fileadmin/site/umwelthemen/abfall/ROHS/finalresults/Annex6\\_RoHS\\_AnnexII\\_Dossier\\_DEHP.pdf](http://www.umweltbundesamt.at/fileadmin/site/umwelthemen/abfall/ROHS/finalresults/Annex6_RoHS_AnnexII_Dossier_DEHP.pdf)

- AD. whereas the Commission is accountable to the European public for protecting citizens and the environment from hazardous chemicals, while promoting innovation, including in the area of safer chemicals and products to foster a resilient economy;
1. Considers that the draft Commission implementing decision exceeds the implementing powers provided for in Regulation (EC) No 1907/2006;
  2. Calls on the Commission to withdraw its draft implementing decision and to submit a new draft rejecting the applications for authorisation for the formulation of recycled soft PVC containing DEHP;
  3. Calls on the Commission to swiftly end the use of DEHP in all remaining applications, all the more so because safer alternatives to soft PVC and to DEHP are widely available;
  4. Instructs its President to forward this resolution to the Council and the Commission, and to the governments and parliaments of the Member States.