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B8-0218/2019

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MOTION FOR A RESOLUTION

pursuant to Rule 106(2) and (3) of the Rules of Procedure

on the draft Commission implementing decision partially granting an authorisation for certain uses of bis(2-ethylhexyl) phthalate (DEHP) under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (DEZA a.s.)
(D060865/01 – 2019/2605(RSP))

Committee on the Environment, Public Health and Food Safety

Members responsible: Pavel Poc, Bas Eickhout, Kateřina Konečná

B8-0218/2019

European Parliament resolution on the draft Commission implementing decision partially granting an authorisation for certain uses of bis(2-ethylhexyl) phthalate (DEHP) under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (DEZA a.s.)
(D060865/01 – 2019/2605(RSP))

The European Parliament,

– having regard to the draft Commission implementing decision partially granting an authorisation for certain uses of bis(2-ethylhexyl) phthalate (DEHP) under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (DEZA a.s.) (D060865/01),

– 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] ('the REACH Regulation'), and 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)[2], pursuant to the third subparagraph of Article 64(5) of Regulation (EC) No 1907/2006,

– having regard to Commission Regulation (EU) 2018/2005 of 17 December 2018 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)[3],

– having regard to Articles 11 and 13 of 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[4],

– having regard to its 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

[1] OJ L 396, 30.12.2006, p. 1.
[2] RAC and SEAC Opinions for use 1: https://echa.europa.eu/documents/10162/60f338a5-09ac-423a-b7c1-2511ee2d9b77; for use 2: https://echa.europa.eu/documents/10162/1ce96eb6-9e30-447d-a9ff-dc315f75f124 ; for use 3: https://echa.europa.eu/documents/10162/bfbf6ddc-dd94-456b-bbff-32d7d32e6c92
[3] OJ L 322, 18.12.2018, p. 14.
[4] OJ L 55, 28.2.2011, p. 13.

and of the Council[5],

– having regard to the judgment of the General Court of the European Union in Case T-837/16[6],

– having regard to the motion for a resolution of the 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 was added to the candidate list of substances of very high concern under the REACH Regulation in 2008[7] because of its classification as toxic to reproduction;

B. whereas DEHP was included in Annex XIV of the REACH Regulation in 2011[8] due to that classification its widespread use and high volume of production in the Union[9], with a sunset date of 21 February 2015;

C. whereas companies willing to continue using DEHP had to submit an application for authorisation by August 2013; whereas DEZA, having submitted its application before that deadline, was allowed to continue using DEHP pending the authorisation decision provided for in Article 58 of the REACH Regulation;

D. whereas the Commission received the opinions of RAC and SEAC in January 2015; whereas the Commission's delay in drafting the decision de facto led to the continued use of DEHP being tolerated for more than four years after the sunset date;

E. whereas DEHP was identified in 2014 as having endocrine disrupting properties for animals and humans; whereas the candidate list was updated accordingly in 2014[10] regarding the environment and in 2017[11] regarding human health;

F. whereas Regulation (EU) 2018/2005 restricted the use of DEHP and other phthalates in many articles based on an unacceptable risk to human health; whereas RAC highlighted, in the context of that restriction, the fact that 'the uncertainty assessment suggests that the hazards and thus the risks from the four phthalates may be underestimated'[12];

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[5] OJ C 366, 27.10.2017, p. 96.

[6] http://curia.europa.eu/juris/documents.jsf?oqp=&for=&mat=or&lgrec=en&jge=&td=%3BALL&jur=C%2CT%2CF&num=T-837%252F16&page=1&dates=&pcs=Oor&lg=&pro=&nat=or&cit=none%252CC%252CCJ%252CR%252C2008E%252C%252C%252C%252C%252C%252C%252C%252C%252C%252Ctrue%252Cfalse%252Cfalse&language=en&avg=&cid=2535071

[7] https://echa.europa.eu/documents/10162/c94ac248-378f-4058-9907-205b497c286e

[8] Commission Regulation (EU) No 143/2011 of 17 February 2011 amending Annex XIV to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (OJ L 44, 18.2.2011, p. 2).

[9] https://echa.europa.eu/documents/10162/6f89a308-c467-4836-ae1e-9c6163a9ae10

[10] https://echa.europa.eu/documents/10162/30b654ce-1de3-487a-8696-e05617c3173b

[11] https://echa.europa.eu/documents/10162/88c20879-606b-03a6-11e4-9edb90e7e615

[12] 'The uncertainty assessment suggests that the hazards and thus the risks from the four phthalates may be underestimated. The DNELs for DEHP and BBP may be lower than currently derived. A number of experimental and epidemiological studies have suggested possible effects on the immune system, the metabolic system and neurological development. Some of these studies indicate that reproductive toxicity may not be the

G. whereas Regulation (EU) 2018/2005 exempts certain applications insofar as they are not deemed to present an unacceptable risk to human health; whereas apart from the export of DEHP-containing formulations, the draft Commission implementing decision is therefore of particular relevance for those exempted applications;

H. whereas such applications could, however, represent an unacceptable risk to the environment, in particular due to the endocrine disrupting properties of DEHP;

I. whereas the primary objective of the REACH Regulation is to ensure a high level of protection of human health and the environment in light of its recital 16, as interpreted by the Court of Justice of the European Union[13];

J. whereas according to Article 55 and recital 12 of the REACH Regulation, the replacement of substances of very high concern with suitable alternative substances or technologies is a central aim of authorisation;

K. whereas point (d) of Article 62(4) of the REACH Regulation requires the applicant to provide a chemical safety report in accordance with Annex I;

L. whereas in this case the RAC opinion identified major deficiencies in the information provided by the applicant [14]; whereas for one use no information was provided at all[15];

M. whereas the RAC and the Commission concluded that the applicant failed to demonstrate that the risk was adequately controlled under Article 60(2); whereas RAC also concluded that, contrary to Article 60(10), the risk was not reduced to as low a level as is technically and practically possible;

N. whereas the draft Commission implementing decision refuses authorisation for the one use for which no information was provided in the application, on the basis of Article 60(7) of the REACH Regulation;

O. whereas the draft Commission implementing decision elsewhere acknowledges the deficiencies indicated by RAC by referring to 'limited information submitted on workplace exposure',[16] but instead of similarly rejecting the authorisation in accordance with Article 60(7), requires the applicant to provide the missing data in its review report

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most sensitive endpoint and that the selected DNELs may not be sufficiently protective against these other effects. Moreover, the Member State Committee (MSC) has confirmed that these four phthalates are endocrine disruptors related to human health and the Commission is considering to identify them as substances of equivalent concern under Article 57(f) of REACH. This raises additional uncertainties with the risk of these substances.' See https://www.echa.europa.eu/documents/10162/713fd91d-2919-0575-836a-f66937202d66, p. 9.

[13] Case C-558/07, *S.P.C.M. SA and Others* v *Secretary of State for the Environment, Food and Rural Affairs*, ECLI:EU:C:2009:430, paragraph 45.

[14] 'RAC evaluates that the exposure data presented in the CSR are not representative for the extensive scope of the application. Therefore, a well-founded exposure assessment by RAC is not possible. The following evaluations are only based on a deficient data base and by this [are] of little significance for the following risk assessment'- see RAC opinion on use 2, p. 10: https://echa.europa.eu/documents/10162/1ce96eb6-9e30-447d-a9ff-dc315f75f124

[15] Draft decision, paragraph 19.

[16] Draft decision, paragraph 17.

18 months after adoption of the decision[17];

P. whereas the review report provided for in Article 61 is not intended to give more time to companies to fill gaps in information that had to be provided initially, but is meant to ensure that the information initially provided in the application is still up-to-date after a set period, including, in particular, as regards whether new alternatives have become available;

Q. whereas the General Court clearly stated that conditions to an authorisation, within the meaning of Article 60(8) and (9), cannot be legally used to remedy the potential failures or gaps in the information provided by the applicant for authorisation[18];

R. whereas Article 60(4) provides for an obligation to show that the socio-economic benefits of using the substance outweigh the risk to human health or the environment and that no suitable alternative substances are available;

S. whereas the SEAC opinion highlighted significant deficiencies in the socio-economic analysis presented by the applicant, also reflected in the draft Commission implementing decision[19];

T. whereas, in light of Article 55 and Article 60(4), an applicant must prove that there are no suitable alternatives to the uses it has applied for;

U. whereas the draft Commission implementing decision acknowledges that use 2 was not specific enough[20]; whereas SEAC found severe deficiencies in the application with regard to the availability of alternatives[21,22];

V. whereas it is not a legitimate justification for the applicant to rely on its status as manufacturer of the substance to fail to provide sufficient information on the suitability of alternatives for the uses covered in the application;

W. whereas due to the deficient data provided a member of SEAC officially disagreed with the conclusion of SEAC on the lack of suitable alternatives[23];

X. whereas Article 60(5) cannot be interpreted to mean that the suitability of the alternatives from the perspective of the applicant is the unique and determinant factor; whereas Article 60(5) does not set an exhaustive list of the information to be taken into account in the analysis of alternatives; whereas point (c) of Article 60(4) also requires that information from third party contributions be taken into account; whereas

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[17] Draft decision, paragraph 17
[18] Judgment of the General Court on 7 March 2019, Sweden v. Commission, Case T-837/16, §82-83
[19] 'a quantitative assessment of the human health impact of the continued use was not possible due to limitations in the available information' - Draft authorisation, paragraph 5
[20] Draft decision, paragraph 18
[21] 'the conclusion of the applicant regarding the suitability and availability of alternatives … is not sufficiently justified' - SEAC Opinion on use 2, p. 18 - https://echa.europa.eu/documents/10162/1ce96eb6-9e30-447d-a9ff-dc315f75f124
[22] 'the assessment of alternatives does not address specifically the varied situations covered by the very broad scope of this application and therefore does not demonstrate that alternatives are not technically feasible' - SEAC Opinion on use 2, p. 19
[23] https://echa.europa.eu/documents/10162/03434073-5619-4395-8293-92ddaf6c85ad

information provided in the public consultation did reveal already at the time the availability of alternatives for uses covered[24];

Y. whereas the General Court reminded the Commission that, in order to legally grant an authorisation under Article 60(4), it has to verify a sufficient amount of substantial and verifiable information in order to conclude either that no suitable alternatives are available for any of the uses covered in the application or that remaining uncertainties on the lack of available alternatives, at the date of the adoption of the authorisation, are negligible[25];

Z. whereas the draft Commission implementing decision gives having taken into account 'the new available information from the restriction process'[26] as a reason for the delay in its adoption; whereas it is therefore surprising that the draft Commission implementing decision has failed to consider the availability of alternatives that is clearly documented in the restriction dossier[27]; whereas alternatives mentioned in the restriction proposal are also relevant for uses covered in the draft Commission implementing decision[28];

AA. whereas, finally, the Commission did not take into account the fact that DEHP has been officially recognised as an endocrine disruptor affecting human health and the environment; whereas this information ought to have been taken into account by the Commission in the context of the socio-economic assessment under Article 60(4), as the benefits of a refusal to authorise are otherwise underestimated;

AB. whereas the authorisation proposed by the Commission is thus in breach of Article 60(4) and 60(7) of the REACH Regulation;

AC. whereas the draft Commission implementing decision would reward laggards, and negatively affect companies which have invested in alternatives[29];

AD. whereas the draft Commission implementing decision states that 'the Commission took note' of the resolution of the European Parliament of 25 November 2015; whereas many of the structural flaws in the implementation of the authorisation chapter of the REACH Regulation that Parliament highlighted in that resolution also vitiate the present draft Commission implementing decision;[30]

AE. whereas the European Parliament, in its resolution of 13 September 2018 on the implementation of the circular economy package: options to address the interface

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[24] https://echa.europa.eu/comments-public-consultation-0004-02 - see in particular line 58;
[25] Judgment of the General Court of 7 March 2019, *Sweden* v *Commission*, EU:T:2019:144, §86
[26] Draft authorisation, paragraph 3.
[27] 'Technically feasible alternatives with lower risk are currently available at similar prices for all uses in the scope of this proposal' - https://www.echa.europa.eu/documents/10162/713fd91d-2919-0575-836a-f66937202d66
[28] https://www.echa.europa.eu/documents/10162/713fd91d-2919-0575-836a-f66937202d66 - p. 69; see 'applications' in the table, also covering outdoor uses.
[29] See for example: https://marketplace.chemsec.org/Alternative/Non-phthalate-plasticizer-for-extreme-applications-302; https://marketplace.chemsec.org/Alternative/Safe-plasticizer-for-demanding-outdoor-applications-298; http://grupaazoty.com/en/wydarzenia/plastyfikatory-nieftalanowe.html
[30] See in particular recitals N, O, P and R of that resolution.

between chemical, product and waste legislation'[31], reiterated that 'moving towards a circular economy requires strict application of the waste hierarchy and, where possible, phasing out of substances of concern, in particular where safer alternatives exist or will be developed';

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 application for authorisation;

3. Calls on the Commission to end swiftly the use of DEHP in all remaining applications, especially given the fact that safer alternatives to soft PVC and to DEHP are 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.

[31] Texts adopted, P8_TA(2018)0353.