



Brussels, 16.6.2016
C(2016) 3549 final

COMMISSION IMPLEMENTING DECISION

of 16.6.2016

**granting an authorisation for uses of bis(2-ethylhexyl) phthalate (DEHP) under
Regulation (EC) No 1907/2006 of the European Parliament and of the Council**

(Text with EEA relevance)

[ONLY THE ENGLISH TEXT IS AUTHENTIC]

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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/EC¹, and in particular Article 64(8) thereof,

Whereas:

- (1) Bis(2-ethylhexyl) phthalate (DEHP) (hereinafter referred to as “DEHP”) is listed in Annex XIV to Regulation (EC) No 1907/2006 and therefore subject to the authorisation requirement referred to in Article 56(1) of that Regulation.
- (2) An application for authorisation was jointly submitted by VinyLoop Ferrara S.p.A, Stena Recycling AB and Plastic Planet srl (‘the applicants’) on 13 August 2013 in accordance with Article 62 of Regulation (EC) No 1907/2006, for two uses of DEHP, namely the formulation of recycled soft poly(vinyl chloride) (PVC) containing DEHP in compounds and dry-blends and the industrial use of recycled soft PVC containing DEHP in polymer processing by calendaring, extrusion, compression and injection moulding to produce PVC articles.
- (3) On 24 October 2014 the European Chemicals Agency sent to the Commission 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.
- (4) On 25 November 2015 the European Parliament adopted a non-legislative resolution³ concerning this authorisation for uses of DEHP. The Commission took note of that resolution.

¹ OJ L 396, 30.12.2006, p. 1.

² http://echa.europa.eu/documents/10162/b50d9fc3-f6db-4e91-8a95-c8397bb424d2_and
<http://echa.europa.eu/documents/10162/8d9ee7ac-19cf-4b1a-ab1c-d8026b614d7a>

³ P8_TA-PROV(2015)0409

- (5) According to the RAC opinions, based on the information provided in the application, the applicants did not demonstrate that the risks to workers' health from the two uses applied for are adequately controlled in accordance with Article 60(2) of Regulation (EC) No 1907/2006. It is therefore not appropriate to grant the authorisation based on that provision, although RAC acknowledged that the risks to human health of the general population resulting from the use of DEHP in PVC articles covered by the application are adequately controlled.
- (6) Considering that adequate control of risks was not demonstrated, and that the RAC could not quantify the risks for workers from the two uses of DEHP applied for based on the information provided in the application, in its opinions, the SEAC conducted a qualitative assessment of the remaining risks posed by the two uses of the substance and of the socio-economic arguments in the application related to the benefits arising from those uses for the applicant, his downstream users and society. Based on that assessment, the SEAC concluded that the socio-economic benefits arising from the two uses applied for outweigh the risks to human health arising from those uses. Furthermore the SEAC concluded that at present there are no suitable alternative substances or technologies for those two uses in terms of their technical and economic feasibility for the applicants and some of their downstream users in accordance with Article 60(4) of Regulation (EC) No 1907/2006.
- (7) It is therefore appropriate to authorise these two uses based on Article 60(4) of Regulation (EC) No 1907/2006 provided that the risk management measures and operational conditions described in the application, in particular in the respective chemical safety reports, are fully applied. The authorisation should explicitly exclude the uses not covered by those reports, namely cases where the DEHP content in recycled soft PVC exceeds 20% w/w, the uses advised against and the uses specifically excluded from the application dossier.
- (8) Regulation (EC) No 1907/2006 does not apply to waste as defined in Directive 2008/98/EC of the European Parliament and of the Council⁴. Accordingly, the authorisation to place on the market and use recycled soft PVC compounds and dry-blends containing DEHP in accordance with Article 64 of that Regulation applies to the extent that those compounds and dry-blends have ceased to be waste in accordance with Article 6 of that Directive.
- (9) In its opinions, the SEAC recommended the time-limited review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 to be set at seven years. SEAC took into account the lack of suitable alternatives for the applicants and their downstream users currently and in the next decade for the uses applied for, the fact that the presence of DEHP in waste streams will continue for many years as well as the long investment cycles in the recycling industry. SEAC considered the significant economic costs for the applicants and their downstream users of no longer being able to use the substance resulting from PVC waste recycling, the probable loss of jobs and the external costs for society associated with the environmental and human health damage due to increased landfilling and incineration, reduced recycling rates in case of no authorisation. Nevertheless, the SEAC recognised the deficiencies in the workplace exposure assessment identified by the RAC and the lack of a health impact assessment in the socio-economic analysis.

⁴ 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).

- (10) Due to those deficiencies in the workplace exposure assessment it is therefore appropriate to set the review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 at four years as from the sunset date set out in Annex XIV to Regulation (EC) No 1907/2006 for DEHP.
- (11) In their opinions, the RAC and the SEAC did not recommend any additional conditions, additional risk management measures or operational conditions, nor additional monitoring arrangements compared to those described in the application. However, in the light of the deficiencies in the workplace exposure assessment identified by the RAC in its opinions, the review report to be submitted in accordance with Article 61(1) of Regulation (EC) No 1907/2006 should contain additional specific worker exposure information from representative downstream user workplaces where the uses take place, in order to allow for a more comprehensive evaluation of the risks from the use of the substance at the time of the review. Given the importance of this data for ensuring that the risk management measures in place are effective and appropriate in limiting the risks to workers, the authorisation holders and their downstream users covered by this authorisation should collect this exposure information and keep it available for the enforcement authorities where the uses take place.
- (12) Directive 2011/65/EU of the European Parliament and of the Council⁵ as amended by Commission Delegated Directive (EU) 2015/863⁶ restricts DEHP in PVC (including recycled PVC) in electrical and electronic equipment placed on the market from 22 July 2019. For some categories of electrical and electronic equipment where DEHP in PVC (including recycled PVC) is also used, the restriction applies from 22 July 2021. Any authorisation decision should be in line with that restriction, in particular to ensure compliance with Article 58 of Regulation (EC) No 1907/2006. This is relevant in case a review report pursuant to Article 61(1) of Regulation (EC) No 1907/2006 is submitted.
- (13) The language used for the description of the risk management measures and operational conditions included in the application for authorisation may be different from the official language(s) of the Member State(s) where the use(s) take(s) place. Therefore, in order to facilitate the enforcement of the authorisation, it is appropriate to include a monitoring arrangement requiring the holders of the authorisation to submit a succinct summary of those risk management measures and operational conditions in an official language of the Member State(s) concerned.
- (14) To ensure a proper interaction between the provisions on authorisation and restriction in Regulation (EC) No 1907/2006 and in order to preserve the efficient functioning of the internal market and the protection of human health, safety and the environment, existing restrictions for the use of DEHP in that Regulation and new restrictions referred to in Article 58(6) of that Regulation for the use of DEHP in articles should prevail over the authorisations granted for uses of that substance.

⁵ Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (OJ L 174, 1.7.2011, p. 88).

⁶ 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).

(15) The measures provided for in this Decision are in accordance with the opinion of the Committee established under Article 133 of Regulation (EC) No 1907/2006,

HAS ADOPTED THIS DECISION:

Article 1

An authorisation is granted to the legal entities referred to in Article 4 in accordance with Article 60(4) of Regulation (EC) No 1907/2006 for the following uses of DEHP (EC No. 204-211-0, CAS No. 117-81-7), subject to full application of the risk management measures and operational conditions described in the chemical safety report submitted pursuant to Article 62(4)(d) of that Regulation⁷, corresponding to each respective use and under the condition that the content of DEHP in recycled soft PVC in compounds and dry-blends authorised by this decision does not exceed 20 % w/w.

The authorised uses are identified by the following authorisation numbers allocated to the following legal entities:

[REACH/16/2/0]	Vinyloop Ferrara S.p.A.	Use: formulation of recycled soft poly(vinyl chloride) (PVC) containing DEHP in compounds and dry-blends.
[REACH/16/2/1]	Stena Recycling AB	
[REACH/16/2/2]	Plastic Planet srl	
[REACH/16/2/3]	Vinyloop Ferrara S.p.A.	Use: industrial use of recycled soft PVC containing DEHP in polymer processing by calendaring, extrusion, compression and injection moulding to produce PVC articles except: toys and childcare articles; erasers; adult toys (sex toys and other articles for adults with intensive contact with mucous membranes); household articles smaller than 10 cm that children can suck or chew on; consumer textiles/clothing intended to be worn against the bare skin; cosmetics and food contact materials regulated under sector-specific Union legislation
[REACH/16/2/4]	Stena Recycling AB	
[REACH/16/2/5]	Plastic Planet srl	

Article 2

The review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 shall expire on 21 February 2019.

Article 3

The following monitoring arrangements referred to in Article 60(9)(f) of Regulation (EC) No 1907/2006 shall apply:

⁷ <http://echa.europa.eu/documents/10162/d141e4e0-6e73-44c9-b7e7-957d72d997ae>

- (a) on request by the competent authority of a Member State where an authorised use takes place, the holder of the authorisation shall submit to that authority a succinct summary of the applicable risk management measures and operational conditions referred to in Article 1, in an official language of that Member State.
- (b) The authorisation holders and their downstream users to whom this Decision applies by virtue of Article 56(2) of Regulation (EC) No 1907/2006 shall obtain or otherwise have available up-to-date measurement data (air monitoring and biomonitoring) of worker exposure to DEHP at the workplace for their uses referred to in Article 1, as well as a description of their associated risk management measures and operational conditions. They shall provide that information, upon request, to the national competent authorities where the use takes place. Downstream users shall make that information available to the European Chemicals Agency, at the latest by 31 December 2016, for transmission to the authorisation holders for the purpose of preparing the review report referred to in Article 61(1) of Regulation (EC) No 1907/2006.
- (c) The authorisation holders shall include the following information in the review report referred to in Article 61(1) of Regulation (EC) No 1907/2006:
 - (1) the information received in accordance with point (b), specifying the geographical location and the user category, within the life-cycle of the substance up to its end-use;
 - (2) up-to-date information about the content of DEHP (% w/w) in recycled soft PVC in compounds and dry-blends authorised by this decision.

Article 4

This Decision is addressed to the following:

- (1) VinyLoop Ferrara S.p.A.
Via Marconi, 73
44100 Ferrara
Italy
- (2) Stena Recycling AB
Fiskhammsgatan 8
400 40 Göteborg
Sweden

(3) Plastic Planet srl
Via N. Copernico 16
35013 Cittadella
Italy

Done at Brussels, 16.6.2016

For the Commission
Elżbieta BIEŃKOWSKA
Member of the Commission

