EUROPEAN
COMMISSION

Brussels, XXX
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COMMISSION IMPLEMENTING DECISION

of XXX

granting an authorisation for uses of dibutyl phthalate (DBP) 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/EC[1], and in particular Article 64(8) thereof,

Whereas:

(1) Dibutyl phthalate (hereinafter referred to as "DBP") 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 submitted by Deza a.s. ("the applicant") on 13 August 2013 in accordance with Article 62 of Regulation (EC) No 1907/2006, for three uses of DBP, namely its use as an absorption solvent in a closed system in the manufacture of maleic anhydride (hereinafter referred to as "use 1"), industrial use of DBP as a burning rate surface moderant, plasticiser and/or coolant in the formulation of nitrocellulose-based propellant grains, as well as the industrial use of DBP-containing propellant grains in manufacture of ammunition for military and civilian uses, and pyrocartridges for aircraft ejection seat safety systems (hereinafter referred to as "use 2") and the industrial use of DBP in ceramic sheets and printing pastes for production of capacitors and lamba sensor elements (hereinafter referred to as "use 3"). As specified in the application, no consumer use of DBP or its mixtures is covered by use 2, so that this use does not cover propellants intended for manual, private reloading of ammunition cartridges by civilian users, e.g. licensed individual sports shooters and hunters. It includes, however, propellants for police force ammunition.

(3) On 9 December 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.

[1] OJ L 396, 30.12.2006, p. 1.

[2] http://echa.europa.eu/documents/10162/3b943b86-18d1-40a3-986c-aadeccb691d0 (use 1)

(4) According to the RAC opinions, the risks to human health from the three uses of DBP applied for are adequately controlled in accordance with Article 60(2) of Regulation (EC) No 1907/2006, provided that the risk management measures and operational conditions as described in the application are adhered to.

(5) It is therefore appropriate to authorise the three uses, provided that the risk management measures and operational conditions described in the application, in particular in the respective chemical safety reports, are fully applied.

(6) Concerning uses 1 and 2, the SEAC recommended the review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 to be set at twelve years. The recommended review period for use 1 takes into account the adequate control of the risks for workers arising from the use of the substance, the lack of suitable alternatives at present, the socio-economic implications for the applicant and its supply chain in the event of no authorisation, the long time period required to transition to a suitable alternative, as well as the demonstrably long investment cycle in the sector. The recommended review period for use 2 takes into account the adequate control of the risks for workers arising from the use of the substance, the lack of suitable alternatives at present in terms of their technical and economic feasibility, the socio-economic implications for the applicant and its supply chain in the event of no authorisation, as well as the long time period required to transition to a suitable alternative due to the long time necessary for research and development as well as for requalification and recertification.

(7) It is therefore appropriate to set the review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 for uses 1 and 2 at twelve years.

(8) Concerning use 3, the SEAC recommended the review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 to be set at four years. The recommended review period takes into account the lack of suitable alternatives at present in terms of their technical feasibility for the applicant's downstream users, but also the uncertainties in the SEAC's assessment of the suitability, and availability of alternatives due to deficiencies in the applicant's analysis of alternatives, the uncertainties about the time needed for substitution for the applicant and its supply chain once a suitable alternative is available and the lack of sufficient justification for the need of a longer period. .

(9) It is therefore appropriate to set the review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 for use 3 at four years.

(10) In their opinions, the RAC and SEAC did not recommend any additional risk management measures and operational conditions, nor additional monitoring arrangements compared to those described in the application.

(11) 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.

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http://echa.europa.eu/documents/10162/b7929356-588b-44b6-ac47-391c3daac023 (use 2)
http://echa.europa.eu/documents/10162/81ccd18d-b392-4297-aed8-2c05dc656d21 (use 3)

(12) 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 in accordance with Article 60(2) of Regulation (EC) No 1907/2006 for the following uses of dibutyl phthalate (DBP) (EC No. 201-557-4, CAS No. 84-74-2), 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 Regulation[3], corresponding to each respective use.

The authorised uses are identified by the following authorisation numbers:

[REACH/15/X/0]	Use: use of DBP as an absorption solvent in a closed system in the manufacture of maleic anhydride
[REACH/15/X/1]	Use: use of DBP in propellants: Formulation: industrial use of DBP as a burning rate surface moderant, plasticiser and/or coolant in the formulation of nitrocellulose-based propellant grains; Use at industrial site: Industrial use of DBP-containing propellant grains in manufacture of ammunition for military and civilian uses, and pyrocartridges for aircraft ejection seat safety systems (includes propellants for police force ammunition and excludes propellants intended for manual, private reloading of ammunition cartridges by civilian users, i.e., licensed individual sports shooters and hunters. No consumer use of DBP or its mixtures is covered by this use)
[REACH/15/X/2]	Use: industrial use of DBP in ceramic sheets and printing pastes for production of capacitors and lambda sensor elements

Article 2

The review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 shall expire on 21 February 2027 for uses 1 and 2 and on 21 February 2019 for use 3.

Article 3

The following monitoring arrangements referred to in Article 60(9)(f) shall apply:

[3] http://ec.europa.eu/DocsRoom/documents/9803/attachments/1/translations/en/renditions/native
http://ec.europa.eu/DocsRoom/documents/9804/attachments/1/translations/en/renditions/native
http://ec.europa.eu/DocsRoom/documents/9805/attachments/1/translations/en/renditions/native

On request of the competent authority of the Member State where the authorised uses take 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 the Member State.

Article 4

This Decision is addressed to DEZA a.s., Masarykova 753, 75728 Valašské Meziříčí, Czech Republic.

Done at Brussels,

For the Commission

Elżbieta BIEŃKOWSKA
Member of the Commission