

Helsinki, 06.07.2017

## Inclusion of substances of very high concern in the Candidate List for eventual inclusion in Annex XIV

(Decision of the European Chemicals Agency)

<p>Owner: Jukka Malm Activity/Process: 03.02 Identification of SVHC Validity: Indefinite Classification: Public</p>	<p>Distribution: Deputy Executive Director Quality Manager HoU D.2 ECHANet</p>
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## Whereas

- 1) Pursuant to Article 59(3) of 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) the European Chemicals Agency (hereinafter referred to as 'ECHA' or 'The Agency') received from Member States two dossiers in accordance with Annex XV to REACH for substances which in their opinion meet the criteria of substances of very high concern (SVHCs) set out in Article 57 of REACH.
- 2) On 09 March 2017, the Agency invited all interested parties to submit comments on the Annex XV dossiers, as stated in Article 59(4) of REACH.
- 3) The public commenting period for all substances ended on 24 April 2017.
- 4) In accordance with Article 59(5) of REACH, the deadline for Member States or the Agency to comment on the identification of the substances as SVHCs was 08 May 2017.
- 5) The Agency received comments on the identification as SVHCs for the following substances:

SUBSTANCE NAME	EC NUMBER	CAS NUMBER
Perfluorohexane-1-sulphonic acid and its salts (PFHxS)	-	-
4,4'-isopropylidenediphenol (bisphenol A; BPA)	201-245-8	80-05-7

- 6) Thus, pursuant to Article 59(7) of REACH the dossiers related to these substances were referred to the Member State Committee (MSC).
- 7) The Member State Committee at its 54th meeting unanimously agreed that the following substances meet the criteria set out in Article 57 of REACH:

SUBSTANCE NAME	EC NUMBER	CAS NUMBER
Perfluorohexane-1-sulphonic acid and its salts (PFHxS)	-	-
4,4'-isopropylidenediphenol (bisphenol A; BPA)	201-245-8	80-05-7

- 8) Therefore, pursuant to Article 59(8) of REACH the Agency shall now include the following substance in the Candidate List for eventual inclusion in Annex XIV to REACH:

SUBSTANCE NAME	EC NUMBER	CAS NUMBER
Perfluorohexane-1-sulphonic acid and its salts (PFHxS)	-	-

- 9) As the substance 4,4'-isopropylidenediphenol (bisphenol A; BPA) is already listed on the Candidate List, this entry shall now be updated, pursuant to Article 59(8) of REACH, to reflect the additional intrinsic properties of concern, i.e. that BPA demonstrates probable serious effects to human health, due to its endocrine disrupting properties, which are of an equivalent level of concern in accordance with Article 57(f) of REACH.
- 10) Pursuant to Article 59(9) of REACH the European Commission was required to take a decision on the identification as SVHCs for the following substances:

SUBSTANCE NAME	EC NUMBER	CAS NUMBER
Benzyl butyl phthalate (BBP)	201-622-7	85-68-7
Bis(2-ethylhexyl) phthalate (DEHP)	204-211-0	117-81-7
Dibutyl phthalate (DBP)	201-557-4	84-74-2

Diisobutyl phthalate (DIBP)	201-553-2	84-69-5
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- 11) As a result the Commission adopted Implementing Decision (EU) C(2017) 4462 of 4 July 2017 identifying benzyl butyl phthalate (BBP), bis(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP) and diisobutyl phthalate (DIBP) as substances having endocrine disrupting properties whose effects to human health give rise to an equivalent level of concern according to Article 57(f) of REACH.
- 12) As these substances are already listed on the Candidate List their entries shall now be updated to reflect the additional intrinsic properties of concern, i.e. that they demonstrate probable serious effects to human health, due to their endocrine disrupting properties, which are of an equivalent level of concern in accordance with Article 57(f) of REACH.
- 13) Furthermore, the terminology used in the Candidate List, regarding the reason for inclusion for substances identified as SVHCs under Article 57(f), will be improved in order to clearly specify the intrinsic property of concern. Therefore, the text concerning "equivalent level of concern" will be replaced by a statement of the intrinsic properties relevant for identification under Article 57(f) in each of the applicable entries.
- 14) In accordance with Article 59(10) of REACH, the Candidate List shall be accordingly updated and published on ECHA's website.

## I HAVE DECIDED THE FOLLOWING:

1. Pursuant to Article 59(8) of REACH the following substance shall be included on 07 July 2017 in the Candidate List for eventual inclusion in Annex XIV to REACH.

SUBSTANCE NAME	EC NUMBER	CAS NUMBER	INTRINSIC PROPERTY(IES) REFERRED TO IN ARTICLE 57
Perfluorohexane-1-sulphonic acid and its salts (PFHxS)	-	-	vPvB (Article 57(e))

2. Pursuant to Article 59(8) of REACH, on 07 July 2017, the following existing entry in the Candidate List for eventual inclusion in Annex XIV to REACH shall be updated with the indicated additional intrinsic properties referred to in Article 57:

SUBSTANCE NAME	EC NUMBER	CAS NUMBER	INTRINSIC PROPERTY(IES) REFERRED TO IN ARTICLE 57
4,4'-isopropylidenediphenol (bisphenol A; BPA)	201-245-8	80-05-7	Endocrine disrupting properties (Article 57(f) - human health)

3. Pursuant to Article 59(10) of REACH, on 07 July 2017, the Agency shall publish and update on its website the Candidate List for eventual inclusion in Annex XIV to REACH with the following entries:

SUBSTANCE NAME	EC NUMBER	CAS NUMBER	INTRINSIC PROPERTY(IES) REFERRED TO IN ARTICLE 57
Perfluorohexane-1-sulphonic acid and its salts (PFHxS)	-	-	vPvB (Article 57(e))
Benzyl butyl phthalate (BBP)	201-622-7	85-68-7	Endocrine disrupting properties (Article 57(f) – human health)
Bis(2-ethylhexyl) phthalate (DEHP)	204-211-0	117-81-7	Endocrine disrupting properties (Article 57(f) – human health)
Dibutyl phthalate (DBP)	201-557-4	84-74-2	Endocrine disrupting properties (Article 57(f) – human health)
Diisobutyl phthalate (DIBP)	201-553-2	84-69-5	Endocrine disrupting properties (Article 57(f) – human health)
4,4'-isopropylidenediphenol (bisphenol A; BPA)	201-245-8	80-05-7	Endocrine disrupting properties (Article 57(f) - human health)

4. For all current Candidate List entries for substances identified under Article 57(f) the reason for inclusion shall be amended as follows:
  - a) Equivalent level of concern having probable serious effects to human health (Article 57 f) to either Endocrine disrupting properties (Article 57(f) - human health) or Respiratory sensitising properties (Article 57(f) – human health) or Specific target organ toxicity after repeated exposure (Article 57(f) – human health).
  - b) Equivalent level of concern having probable serious effects to the environment to Endocrine disrupting properties (Article 57(f) – environment)

## 5. Publication

The updated Candidate List shall be published on ECHA's website on 07 July 2017.

*(e-signed)*

Jukka Malm<sup>1</sup>  
Deputy Executive Director<sup>2</sup>

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<sup>1</sup> Mandated to sign this decision pursuant to the decision of the Executive Director ED/20/2015 delegating the power to sign decisions to include a substance on the Candidate List for eventual inclusion in Annex XIV under Article 59(6) or Article 59(8) of the REACH Regulation to Jukka Malm, Deputy Executive Director.

<sup>2</sup> As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.