

Helsinki, 04.01.2017

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

**(Decision of the European Chemicals Agency)**

<p><b>Owner: Jukka Malm</b> <b>Activity/Process: 03.02</b> <b>Identification of SVHC</b> <b>Validity: Indefinite</b> <b>Classification: Public</b></p>	<p><b>Distribution:</b> <b>Deputy Executive Director</b> <b>Quality Manager</b> <b>HoU D.2</b> <b>ECHAnet</b></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 six 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 06 September 2016, 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 21 October 2016.
- 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 07 November 2016.
- 5) The Agency received comments on the identification as SVHCs for the following substances:

SUBSTANCE NAME	EC NUMBER	CAS NUMBER
4,4'-isopropylidenediphenol (bisphenol A; BPA)	201-245-8	80-05-7
Nonadecafluorodecanoic acid (PFDA) and its sodium and ammonium salts	206-400-3	335-76-2
	-	3830-45-3
	221-470-5	3108-42-7
4-tert-butylphenol	202-679-0	98-54-4
<i>p</i> -(1,1-dimethylpropyl)phenol	201-280-9	80-46-6
Benzene-1,2,4-tricarboxylic acid 1,2-anhydride (trimellitic anhydride; TMA)	209-008-0	552-30-7
4-heptylphenol, branched and linear [substances with a linear and/or branched alkyl chain with a carbon number of 7 covalently bound predominantly in position 4 to phenol, covering also UVCB- and well-defined substances which include any of the individual isomers or a combination thereof]	-	-

- 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 MSC unanimously agreed via written procedure, which closed on 02 December 2016 that the following substances meet the criteria set out in Article 57 of REACH for identification as SVHC:

SUBSTANCE NAME	EC NUMBER	CAS NUMBER
4,4'-isopropylidenediphenol (bisphenol A; BPA)	201-245-8	80-05-7
Nonadecafluorodecanoic acid (PFDA) and its sodium and ammonium salts	206-400-3	335-76-2
	-	3830-45-3
	221-470-5	3108-42-7

- 8) Therefore, pursuant to Article 59(8) of REACH the Agency shall now include these substances in the Candidate List for eventual inclusion in Annex XIV to REACH.
- 9) The Member State Committee at its 51<sup>st</sup> meeting unanimously agreed that the following substances meet the criteria set out in Article 57(f) of REACH:

<b>SUBSTANCE NAME</b>	<b>EC NUMBER</b>	<b>CAS NUMBER</b>
<i>p</i> -(1,1-dimethylpropyl)phenol	201-280-9	80-46-6
4-heptylphenol, branched and linear [substances with a linear and/or branched alkyl chain with a carbon number of 7 covalently bound predominantly in position 4 to phenol, covering also UVCB- and well-defined substances which include any of the individual isomers or a combination thereof]	-	-

10) Therefore, pursuant to Article 59(8) of REACH the Agency shall now include these substances in the Candidate List for eventual inclusion in Annex XIV to REACH.

11) The Member State Committee at its 51<sup>st</sup> meeting did not unanimously agree that the following substances meet the criteria set out in Article 57(f) of REACH:

<b>SUBSTANCE NAME</b>	<b>EC NUMBER</b>	<b>CAS NUMBER</b>
Benzene-1,2,4-tricarboxylic acid 1,2-anhydride (trimellitic anhydride; TMA)	209-008-0	552-30-7
4-tert-butylphenol	202-679-0	98-54-4

12) Therefore these substances shall not be included in the Candidate List. The Member State Committee's majority opinion in support of the identification of the substances as substances of very high concern and the minority views shall in accordance with Article 59(9) of REACH be referred to the European Commission for final decision-making.

13) In accordance with Article 59(10) of REACH, the updated Candidate List shall be published on ECHA's website.

## I HAVE DECIDED THE FOLLOWING:

1. Pursuant to Article 59(8) of REACH the following substances shall be included on 12 January 2017 in the Candidate List for eventual inclusion in Annex XIV to REACH.

SUBSTANCE NAME	EC NUMBER	CAS NUMBER	REASON FOR INCLUSION
4,4'-isopropylidenediphenol (bisphenol A; BPA)	201-245-8	80-05-7	Toxic for reproduction (Article 57c)
Nonadecafluorodecanoic acid (PFDA) and its sodium and ammonium salts	206-400-3 - 221-470-5	335-76-2 3830-45-3 3108-42-7	Toxic for reproduction (Article 57c) PBT (Article 57d)
p-(1,1-dimethylpropyl)phenol	201-280-9	80-46-6	Equivalent level of concern having probable serious effects to environment (Article 57f)
4-heptylphenol, branched and linear [substances with a linear and/or branched alkyl chain with a carbon number of 7 covalently bound predominantly in position 4 to phenol, covering also UVCB- and well-defined substances which include any of the individual isomers or a combination thereof]	-	-	Equivalent level of concern having probable serious effects to environment (Article 57f)

## 2. Publication

The updated Candidate List shall be published on ECHA's website on 12 January 2017.

*(e-signed)*

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

<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.