



EEB comments on the identification of 6 Substances of Very High Concern

ECHA Public Consultation on SVHC Identification, October 2023

Submitted to ECHA: October 16, 2023

ECHA launched a Public Consultation on six new proposals for the identification of Substances of Very High Concern (SVHC) with serious and irreversible effects on human health or the environment. The proposals will be further discussed at the Member State Committee meeting in December 2023. EEB submitted comments in the Public Consultation to support the SVHC identification.

1. **2,4,6-tri-*tert*-butylphenol (2,4,6-TTBP)**

EC: 211-989-5

Toxic for reproduction (Article 57c); PBT (Article 57d); vPvB (Article 57e)

Belgium

The EEB supports the proposal by Belgium to identify **2,4,6-tri-*tert*-butylphenol (2,4,6-TTBP)** as a Substance of Very High Concern due to its toxicity for reproduction, as well as its PBT and vPvB properties. 2,4,6-TTBP meets the criteria for reprotoxicity due to its harmonised classification under the CLP regulation as toxic for reproduction, category 1B (H360D: May damage the unborn child). The P and vP criteria are met based on the weight of evidence assessment of all available information, including an inherent degradation test confirming lack of degradation and a test with seawater indicating a half-life > 90 days. 2,4,6-TTBP also fulfills the criteria for B and vB in REACH Annex XIII based on available evidence including experimental BCFs in the range of 4300 to > 23000 L/kg. It meets the toxicity criteria for PBT substances owing to its harmonised classification as reprotox 1B and STOT RE 2. Therefore, based on

the weight of evidence assessment, the substance meets the criteria for PBT and vPvB substances. The EEB recommends considering the inclusion of multi-constituent substances and mixtures containing 2,4,6-TTBP in the candidate list.

2. 2-(2H-benzotriazol-2-yl)-4-(1,1,3,3-tetramethylbutyl)phenol (UV-329)

EC: 221-573-5

vPvB (Article 57e)

Germany

The EEB welcomes the proposal by Germany to identify 2-(2H-benzotriazol-2-yl)-4-(1,1,3,3-tetramethylbutyl)phenol (UV-329) as a Substance of Very High Concern due to its vPvB properties (REACH article 57e). We agree with the assessment of the dossier submitter that the substance meets the criteria for very persistent and very bioaccumulative properties of REACH Annex XIII taking into account all weight of evidence, including the use of read-across from other structurally related UV-benzotriazoles. The lack of degradation in a sediment-water simulation test, corresponding to a half-life of over 212 days and the presence of the structurally similar UV-P in sediment core samples of several decades old confirm the vP property. UV-329 meets the vB criterion based on the assessment of all weight of evidence, including a BCF of 12000 L/kg determined in *Hyalella azteca*. The detection of UV-329 in human breast milk and in biota in remote areas, including top predators like polar bears add to the evidence regarding their high bioaccumulation potential. The substance should be included in the Candidate List. Further action on the group of UV-benzotriazoles is urgently needed to prevent regrettable substitution and further emissions into the environment.

3. 2-(dimethylamino)-2-[(4-methylphenyl)methyl]-1-[4-(morpholin-4-yl)phenyl]butan-1-one

EC number: 438-340-0

Toxic for reproduction (Article 57c)

Austria

The EEB thanks Austria for the proposal to identify 2-(dimethylamino) -2-[(4-methylphenyl)methyl]-1-[4-(morpholin-4-yl)phenyl]butan-1-one as Substance of

Very High Concern according to REACH Article 57 (c) due to its classification in the hazard class toxic for reproduction, category 1B (H360Df May damage the unborn child and suspected of damaging fertility), following the upcoming 22nd ATP of the CLP regulation.

4. Bumetrizole (UV-326)

EC 223-445-4

vPvB (Article 57e)

Germany

The EEB supports the proposal by Germany to identify bumetrizole (2-tert-butyl-6-(5-chloro-2H-benzotriazol-2-yl)-4- methylphenol, UV-326)

as a Substance of Very High Concern due to its vPvB properties (REACH article 57e). We agree with the assessment of the dossier submitter that the substance meets the criteria for very persistent and very bioaccumulative properties of REACH Annex XIII considering all weight of evidence, including the use of read-across from other structurally related UV-benzotriazoles. The lack of degradation in a sediment-water simulation test, corresponding to a half-life of over 212 days and the presence in sediment core samples of several decades old confirm the vP property. The experimental BCFs in the range of 7000 - 14000 L/kg confirm the B/vB property, supported also by the detection of UV-326 in breast milk and top predators like polar bears. The substance should be included in the Candidate List. Further action on the group of UV-benzotriazoles is urgently needed to prevent regrettable substitution and further emissions into the environment.

5. Dibutyl phthalate (DBP)

EC number 201-557-4

EDC - environment (Article 57f)

Netherlands

The EEB welcomes the proposal by The Netherlands to identify Dibutyl phthalate (DBP) as substance of very high concern in accordance with Article 57(f) of Regulation (EC) 1907/2006 (REACH) because of its endocrine disrupting properties for which there is

scientific evidence of probable serious effects to human health and the environment which gives rise to an equivalent level of concern to those of other substances listed in points (a) to (e) of Article 57 REACH. The ED effects observed in rats and fish include adverse effects on sexual development, reproduction, survival and growth of offspring and these effects are considered relevant at the population level. There is strong evidence of EAS activity demonstrated by in vitro and in vivo studies and the observed adverse effects are plausibly linked to EAS mode of action. The entry for DBP in the candidate list and Annex XIV should be amended to specify its endocrine disrupting properties for the environment, in addition to its toxicity for reproduction and its endocrine disruption properties for human health.

6. Oligomerisation and alkylation reaction products of 2-phenylpropene and phenol

EC number: 700-960-7

vPvB (Article 57e)

Denmark

The EEB supports the proposal by Denmark to identify the oligomerisation and alkylation reaction products of 2-phenylpropene and phenol as Substances of Very High Concern due to their vPvB properties (REACH article 57e). The dossier submitter demonstrated convincingly that a constituent of the UVCB meets the vPvB criteria based on a weight of evidence assessment.