COMMENTS ON AN ANNEX XV DOSSIER FOR IDENTIFCATION OF A SUBSTANCE AS SVHC AND RESPONSES TO THESE COMMENTS

***Disclaimer**: Comments provided during the consultation are made available as submitted by the commenting parties. It was in the commenting parties own responsibility to ensure that their comments do not contain confidential information. The Response to Comments table has been prepared by the competent authority of the Member State preparing the proposal for identification of a substance of very high concern.*

Substance name: Bis(2-ethylhexyl) tetrabromophthalate covering any of the individual isomers and/or combinations thereof
CAS number: -
EC number: -

The substance is proposed to be identified as meeting the following SVHC criteria set out in Article 57 of the REACH Regulation: vPvB (Article 57e)

PART I: Comments and responses to comments on the SVHC proposal and its justification

General comments on the SVHC proposal

Number / Date	Submitted by (name, submitter type, country)	Comment	Responses
5620 2022/10/12	Norway, Member State	The Norwegian CA supports that Bis(2-ethylhexyl) tetrabromophthalate covering any of the individual isomers and/or combinations thereof should be identified as a substance of very high concern and should be included in the Candidate List. The substance has recently been included in the Norwegian list of substances for priority action based on the same concerns as described in the SVHC-report.	We thank the Norwegian CA for the support.

Specific comments on the justification

Number / Date	Submitted by (name, submitter	Comment	Responses

	type, country)		
5636 2022/10/14	Germany, Member State	The German CA supports the identification of Bis(2- ethylhexyl)-tetrabromophthalate as an SVHC due its vPvB properties.	We thank the German CA for the support.
5669 2022/10/17	Finland, Member State	We thank Sweden for this proposal. We would like to present the following comments on the Annex XV report: On page 7 it is stated "As the isomers are structurally similar, they can be expected to have a reasonably similar vPvB-properties as the whole substance.". This is unclear because the properties of the whole substance are always defined by the properties of the constituents (isomers, in this case). We understand that this note is considered relevant as the available data here are generally for the whole substance and not for the individual isomers. Therefore, please consider linking this to the way the properties were determined, e.g., "As the isomers are structurally similar, and in the absence of other evidence, the properties of the isomers are expected to be reasonably similar to the properties determined for the whole substance". Regarding the water-sediment mesocosm study (de Jourdan et al. 2013), we note that REACH Annex XIII states "(d) Other information, such as information from field	We thank the Finnish CA for the comments. The wording you propose is more accurate and we will amend the dossier as suggested. The P/vP conclusion is based on a weight of evidence (WoE) approach considering all available information related to degradation. Already the ready- and inherent biodegradation tests (which include viable micro-organisms) where very little degradation is seen allows to conclude that TBPH meets the P-criterion and possibly also the vP-criterion. The mesocosm study points in the same direction and adds to the weight of evidence that TBPH is very persistent. The available monitoring data further support the P/vP conclusion in the WoE as TBPH was found in all environmental compartments including air, surface water sediment, and in remote areas such as the Tibetan Plateau and the Arctic. We agree with several of your remarks. It is true that the sediment used was not a natural sediment and thus the representativeness to a natural sediment microorganism community is uncertain. It would have been preferable to use natural sediments instead of creating an artificial one. However, there was a more

		studies or monitoring studies, provided that its suitability and reliability can be reasonably demonstrated.". We consider that the suitability and reliability of this study (de Jourdan et al. 2013) has not been demonstrated. Therefore, we disagree with the statement that this study strongly indicates that TBPH is very persistent in sediment. ECHA guidance R.7b (2017, Version 4.0) states regarding simulation tests: "Aerobic and anaerobic tests that provide data on biodegradation under specified environmentally relevant conditions. These tests attempt to simulate degradation in a specific environment by use of indigenous biomass, media, relevant solids (i.e. soil, sediment, activated sludge or other surfaces) to allow sorption of the substance, and a typical temperature that represents the particular environment." The mesocosm study does not represent a real sediment environment or indigenous biomass of a sediment. The mesocosm study used an artificial sediment containing organics-rich soil (1:1:1 mixture of topsoil:manure:compost organic content 10% dw), thus it does not contain natural sediment at all. The representativeness of the artificial sediment to natural sediments in terms of biodegradation is not discussed in the article. The microorganisms in the artificial sediment originate from the "sediment" itself (soil, manure, and compost), as well as from the	one-year acclimation period before the actual experiment started (the mesocosms were set up in May 2008 and the actual experiment started in July 2009). During this time a microflora more representative of a natural sediment may have been established e.g. by enrichment of microorganisms from the irrigation pond water and from the surrounding environment. Furthermore, in a lab OECD 308 study you can end up with completely different types of sediments in terms of microbial composition (due to physicochemical parameters of the sediment for instance). Therefore, the difference of the microbial composition between the artificial sediment used in this study and any natural sediment, on its own, should not be a good reason for disregarding this study. The study was performed in an open air freely allowing oxygen exchange. and there is no indication of a possible limitation in oxygen concentrations in the test system. Presumably there was also oxygen production from the algae community in the mesocosms. According to personal information from de Jourdan the mean oxygen concentration in the mesocosms during the study period was around 8.5mg/L. Due to the high OC content of the artificial sediment (10% OC instead of the max. recommended of 7.5% in the OECD TG 308 study), it is expected that TBPH has highly adsorbed to the artificial sediment and thus may have limited its bioavailability. In this respect the derived $DissT_{50}$ may represent a worst-case scenario. On the other hand, there seemed to be no problems in extracting TBPH from the sediment. Contrary to this, many other conditions may have favoured dissipation/degradation:

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<td>water (from an irrigation pond supplied by a well) and from the surrounding environment (as this was an open system). Therefore, the representativeness to natural sediment microorganisms is highly uncertain. No microbiological characterization of the sediment (or water) is presented. The physico-chemical characterisation data is limited (11.6% dry total C, 1.6% dry inorganic C, and 10.0% dry organic C). In addition, the oxygen consumption of the artificial sediment and the conditions in the sediment (e.g., oxygen concentration) are not reported.

Because the representativeness (of the biomass, the medium, and the conditions) to the natural environment is highly uncertain, the study does not provide strong evidence for P or vP. For the same reasons, if (hypothetically) a fast degradation was seen in this study, it should still not be used to support non-persistence in sediment (or in any compartment).

We consider that the results of this study are in line with other evidence pointing to persistence of TBPH. However, on its own, this study does not give strong support for persistence of TBPH.

We consider that TBPH fulfills the P criterion based on the other available data. However, it should be further considered whether the vP criterion is fulfilled and, if it is, the relevant</td>
<td>- Temperature. The experiment was performed during summer (July-September). The mean air temperature in the area where the study was performed is normally around 22°C in July, 21 °C in August and 15°C in September and thus the average temperature during the study period was likely much higher than 12°C.
- Pre-exposure of the test system to TBPH. The mesocosms were established in May 2008 and treated with TBPH once in July 2008, one year before the actual 70 day experiment period started with TBPH treatment in July 2009.
-Exposure to sunlight. In contrast to OECD simulation tests which are performed in darkness the mesocosms where exposed to sunlight (as well as wind and rain) which could favour/lead to dissipation from the mesocosm.

Despite these favourable conditions there was clearly no dissipation/degradation of TBPH from the sediment compartment as illustrated by the time weighted average being almost the same as the maximum concentration. Furthermore, no degradation products were identified in the sediment.

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<tr><td></td><td colspan="5">TBPH concentration in the sediment (ng/g OC)</td></tr>
<tr><td></td><td>max</td><td>Arithmetic mean</td><td>Median</td><td>Geometric mean</td><td>Time weighted average</td></tr>
<tr><td>Pond 3</td><td>32.6</td><td>32.6</td><td>32.6</td><td>32.6</td><td>32.5</td></tr>
<tr><td>Pond</td><td>36.8</td><td>34.6</td><td>34.2</td><td>34.6</td><td>35.3</td></tr>
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		sections should be updated regarding the role of the mesocosm study.	12
			To conclude, already the very low degradation in the available ready- and inherent tests are in our view sufficient to conclude P/vP. We admit the mesocosm study has shortcomings, but in our view the conditions for dissipation/degradation seems to be favourable. Despite this no dissipation/degradation of TBPH was observed in the sediment. This adds to the evidence of persistence and taking all information into account we believe that it is motivated to conclude vP. SWE CA agrees to add uncertainties caused by the use of artificial sediment in the de Jourdan et al. (2013) in the support document as explained above. A more thorough discussion of its role in the weight of evidence are provided along with the modified the conclusion of the sediment compartment. *No simulation study is available for TBPH. However, in accordance with REACH Annex XIII Section 3.2.1. (d), a DT50 >200 days from a non-guideline outdoor mesocosm study (reliable with restrictions) is considered in the assessment of P or vP properties of TBPH as part of a weight-of-evidence approach. The study used an artificial sediment with a high organic carbon (OC) content and potentially with different microbial communities (e.g., density and diversity of microorganisms) compared to a natural sediment. However, many other conditions under which the study was conducted favoured dissipation/ degradation. Despite those favourable conditions, there was no dissipation/biodegradation of TBPH in the*

			sediment of this test system. Overall, the study is considered to be relevant for the PBT assessment. The study can be used to show that TBPH is very persistent in the sediment of this test system. Furthermore, the presence of TBPH in all environmental compartments including air, surface water, sediment, and in remote areas such as the Tibetan Plateau and the Arctic, gives further support to conclude that the substance is very recalcitrant to degradation. Overall, based on the available information and considering a weight-of-evidence approach, it is concluded that TBPH is very persistent. Annex XIII, point 3.2.1.(d) of the REACH Regulation requires that any relevant information for the assessment of the persistence of the substances be considered. Therefore, it is concluded that TBPH fulfils the P and vP criterion of REACH Annex XIII.
5696 2022/10/17	ChemSec, International NGO, Sweden	ChemSec supports the SVHC identification of this substance/s, being a vPvB. We added it to the SIN List in 2014. That it is frequesntly found in the environment adds to the urgency for regulatory action.	We thank the ChemSec for the support.
5720 2022/10/17	CHEM Trust Europe, International NGO, Germany	CHEM Trust supports the inclusion of bis(2-ethylhexyl) tetrabromophthalate covering any of the individual isomers and/or combinations thereof in the REACH candidate list based on its very persistent and very bioaccumulative properties. The dossier shows convincingly that the criteria of Annex XIII of the REACH Regulation are fulfilled, thus justifying the	We thank the Chem Trust for the support.

		inclusion via Article 57 (e).	
5726 2022/10/17	European Environmental Bureau (EEB), International NGO, Belgium	The EEB supports the proposal by Sweden to identify Bis(2-ethylhexyl) tetrabromophthalate covering any of the individual isomers and/or combinations thereof (TBPH) as a Substance of Very High Concern due to its vPvB properties (REACH article 57(d)). 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. The detection of TBPH in remote areas ranging from the Canadian Arctic to the Tibetan plateau far away from local sources confirms that the substance is very persistent and has the potential for long range transport. We agree with the approach taken for the diastereoisomer based on the structural similarity of the individual stereoisomers. The substance should be included in the Candidate List and further risk management measures should be implemented to avoid further emissions into the environment.	We thank the EEB for the support.
5738 2022/11/02	Netherlands, Member State	NL supports the proposal to include bis(2-ethylhexyl) tetrabromophthalate covering any of the individual isomers and/or combinations thereof in the candidate list of SVHC in accordance with Article 57(e) of REACH, due to its very persistent and very bioaccumulative properties.	We thank the Netherlands CA for the support. According to the publication the target concentration 500 ng/g was chosen to achieve a concentration in the upper 5 cm of the sediment, consistent with concentrations observed in sewage sludge from the San Francisco Bay area.

		NL agree that the mesocosm biodegradation study performed by de Jourdan et al (2013) indicates that TBPH is very persistent in sediment. For a better understanding of the design and results of this study NL would like to see that it is described in somewhat more detail. For example, why the target concentration of 500 ng/g was chosen and how the substance was measured as well as a more detailed overview of the results. To strengthen the conclusion that TBPH is very persistent in sediment, it could also be emphasised that the formation of degradation products is minor and that the observed (minor) formation of the tribrominated anhydride could be formed via hydrolysis and photolysis .	We will add more details to the description of the study according to your suggestion.

PART II: Comments and responses to comments on uses, exposures, alternatives and risks

Specific comments on use, exposure, alternatives and risks

Number / Date	Submitted by (name, submitter type, country)	Comment	Responses
5696 2022/10/17	ChemSec, International NGO, Sweden	There are a number of alternatives available on the ChemSec Marketplace: https://marketplace.chemsec.org/alternatives/chemical/26040-51-7	Thank you for the information.