16 November 2022

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: 1,1'-[ethane-1,2-diylbisoxy]bis[2,4,6-tribromobenzene]
CAS number: 37853-59-1
EC number: 253-692-3

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
5617 2022/10/12	Norway, Member State	The Norwegian CA supports that 1,1'-[ethane-1,2-diylbisoxy]bis[2,4,6-tribromobenzene] should be identified as a substance of very high concern and should be included in the Candidate List.	Thank you for your support.

Specific comments on the justification

Number / Date	Submitted by (name, submitter type, country)	Comment	Responses
5648 2022/10/14	Sweden, Member State	The Swedish CA thank Spain for this proposal and agrees with the weight-of-evidence determination that BTBPE meets the criteria according to Article 57(e) in REACH and is thus eligible for identification as a substance of very high concern.	Thank you for your support.
5662 2022/10/17	Germany, Member State	The German CA supports the identification of 1,1'-[ethane-1,2-diylbisoxy]bis[2,4,6-tribromobenzene] as SVHC based on its vPvB properties.	Thank you for your support.
5668 2022/10/17	Finland, Member State	We thank Spain for this proposal. We would like to present the following comments regarding the Annex XV report, and in particular regarding the water-sediment mesocosm study (de Jourdan et al. 2013): REACH Annex XIII states "(d) Other information, such as information from field 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. 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,	As indicated in the Annex XV report, we regard the de Jourdan *et al.* 2013 study as reliable with restrictions. The restrictions are further explained below. We agree with your comment that the physico-chemical characterisation data is limited to the organic carbon (OC) content of the artificial sediment (consisting of top soil:manure:compost) instead of natural sediment raises some uncertainties. There is no information on the oxygen concentration and biomass in the mesocosms. Compost and manure could potentially have a high oxygen consumption if they are untreated or treated insufficiently for e.g. application as soil improvement. However, the mesocosms were placed outdoors and to our understanding the

		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 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 also 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	study is referring to open air mesocosms with natural access and availability of oxygen to the water/sediment system which would reflect natural turnover conditions. Based on the measures of dissolved oxygen (DO) provided by B. Jourdan on 07.11.2022, measured in the aquatic phase of the test, there is no indication of a possible limitation in oxygen concentrations in the test system. Based on additional information received from the study authors (de Jourdan, pers. comm.) the oxygen concentration in the water column of the mesocosms remained quite stable and at acceptable levels during the whole 2009 study period (being the geometric mean of the measures 10.55 mg/L for BTBPE during the 70 days after the introduction of the substance to the system). Hence, based on that information and considering the relatively high volume of the water column (12,000 L), there is no indication of a possible limitation in oxygen concentrations in the test system. It is expected that these conditions will be maintained. With regards to pH, information on pH can be obtained from another publication that used the same mesocosm for a bioaccumulation study in 2008 – de Jourdan et al 2014. This shows a pH range of 7-9 with average values being 8.6±0.5 (n=30).

		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 BTBPE. However, on its own, this study does not give strong support for persistence of BTBPE. Therefore, the relevant sections should be updated regarding the role of the water-sediment mesocosm study and the conclusion on persistence in sediment should be reconsidered.	In respect of availability of microorganisms in the system, B. de Jourdan indicated that no microbiological characterisation was done for the artificial sediment. However,the water and the artificial sediment are expected to contain those microorganisms dwelling in the water from an irrigation pond supplied by a well located on site. After setting up the mesocosms, water was circulated from the central irrigation pond into all mesocosms for three weeks at a flow rate of approximately 12 m^3 per 24 h to decrease heterogeneity of water chemistry, zooplankton, and algal assemblages. Circulation was discontinued on June 25 2008, one week prior to the first treatment with the test substances. In 2009 when the mesocosms were re-treated with the susbtances, no new water was added. During the more than one-year acclimation period before the actual experiment started, 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. The measurements of the test substance concentrations in the mesocosms were done in 2009, after the second treatment with the test substances. Before the measurements were taken, the mesocosms had been established over one year, in which time it was maturing,. Hence, it can be expected that the community of

			microorganisms had changed at least to some extent compared to the original community introduced into the system with the soil, manure and compost used to make the artificial sediment. The microbial community had also relatively long time to acclimate to the conditions of the mesocosms. It is acknowledged that the microbial communities (e.g. density and diversity of microorganisms) of the artificial sediment and natural sediment are likely to differ, and hence, the use of natural sediment would have been preferable. However, also in a laboratory OECD TG 308 study it is possible to end up with completely different types of sediments in terms of microbial composition (due to physicochemical parameters of the sediment for instance). In the OECD Guidance document on simulated freshwater lentic field tests (outdoor microcosms and mesocosms) (OECD 2006), it is indicated that natural sediment is preferred in micro and mesocosms but alternatively, soil can be used as the test system sediment, provided that it has been sufficiently conditioned to have aquatic sediment-like properties. According to this guidance document generally this requires a maturation period of immersion of 3 months or more and addition of a small inoculum of aquatic sediment to encourage the development of suitable microflora. It is further stated that if soil is

			used, then additional organisms may need to be added to develop suitable communities for the study. It should be noted that the scope of the OECD (2006) guidance document mainly relates to studies determining environmental effects, and hence the characteristics of the sediment, especially when it comes to the microbial community, are not as crucial as for studies purely aiming to assess degradation. In conclusion, it can be expected that the artificial sediment in the de Jourdan et al. (2003) study contained microorganisms. However, the representativeness of the microbial community to natural sediments cannot be fully known, neither their specific degradation capacity. It should also be noted, that since the mesocosms were treated with the test substances in 2008 but the measurements used to assess the degradation were done after the re-treatment in 2009, the microorganisms in the mesocosms were pre-exposed to the test substance for one year. It has to be noted that even under favouring degradation conditions (cf. possible pre-adaptation of the micro-organisms to the substances), BTBPE appear to be very persistent at the end of the test duration.

			We agree with FI comment that it would have been preferable to add directly sediments to the mesocosm instead of creating an artificial one from an organic-rich soil also consisting of manure and compost. We also acknowledge that the microbial composition in soil and sediment are expected to be different but similarly in a laboratory OECD TG 308 study you can end up with completely different type 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. After one year of maturing, the artificial sediment in the study by de Jourdan *et al.* (2013) could be considered more representative of a surface sediment layer formed. For BTBPE, there is clearly no dissipation/degradation from the sediment compartment as no degradation products have been identified and a relatively constant concentration of both substances was monitored during all the test duration in sediment. Due to the high OC content of the artificial sediment (10% OC instead of the maximum recommended value of 7.5% OC in the

			OECD TG 308), it is expected that the substances have highly adsorbed to the artificial sediment and thus limited their bioavailability and as a consequence the derived DissT50s are likely representing a worst case scenario. However, as mentioned in the Annex XV dossier of BTBPE: 'based on published literature, sediments with organic carbon content above 10% are found in Europe (e.g. Niemirycz *et al.* 2006, Karjalainen *et al.* 2000). Therefore, the de Jourdan *et al.* (2013) study can be considered relevant for assessing persistence in relevant environmental conditions in Europe'. Based on the additional information received from the authors (de Jourdan *et al.* 2013), the geometric mean of the water temperature in the mesocosms during the 2009 study period was 19.6 °C. Converting the half-lives reported in the study for BTBPE to 12 °C, which is considered the environmentally relevant reference temperature under the persistence assessment according to ECHA Guidance Chapter R.11 (Version 3.0, June 2017), results in a half-life of 69 days (95% CI 27-111 days) for the particulate matter and 383 days (95% CI 137-625 days) for the sediment phase. These are well above the vP criteria for water and sediment in Annex XIII of REACH.

			It should be also noted that de Jourdan *et al.* 2013 study is used as part of WoE to support vP conclusion in sediment. For BTBPE, in the overall persistence assessment, more weight is given to the available soil mesocosm study (reliable with restrictions), which indicates vP properties of the substance in soil. The study was run over three years and the BTBPE concentrations were found to be stable over the whole study period. It is therefore considered that the study shows clearly that the half-life of BTBPE in soil is higher than the criteria of 120 and 180 days for a P and vP substance. Furthermore, all available information from QSAR models, screening tests and monitoring studies support the conclusion of P/vP of BTBPE. ES 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 and modify the conclusion of the sediment compartment. *Negligible degradation of BTBPE was also observed in sediment phase in a water-sediment mesocosms study (reliable with restrictions). A sediment DT50 of 187 days for BTBPE (>380 days when converted to 12°C) is reported in the study. This study is not a guideline study and the results have to*

			be treated with care as inhomogeneous distribution in the mesocosms and several processes e.g., sediment-to-water diffusion and resuspension may have influenced the results. The test 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 BTBPE 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 BTBPE is very persistent in the sediment of this test system. The result from this study goes well in line with the other available evidence and adds to the weight-of-evidence indicating that BTBPE fulfils the vP criterion of REACH Annex XIII. Based on the weight of the evidence available and considering the substance is very persistent in the soil compartment, BTPBE is likely to meet the P/vP criteria of REACH Annex XIII in the sediment compartment.

			Therefore, BTPBE is concluded to meet the P/vP criteria of REACH Annex XIII in the soil compartment (degradation half-life in soil > 180 days) and likely meet the P/vP in sediment based on WoE.
5687 2022/10/17	ChemSec, International NGO, Sweden	ChemSec supports the identification of this substance as a vPvB.We added it to the SIN List in 2014, and since the evidence of vPvB properties have grown further. It especially concerning that this substance is allready widespread in the environment.	Thank you for your support.
5719 2022/10/17	CHEM Trust Europe, International NGO, Germany	CHEM Trust supports the inclusion of 1,1'-[ethane-1,2-diylbisoxy]bis[2,4,6-tribromobenzene] 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 inclusion via Article 57 (e). BTBPE is on the SIN list since 2014, based on its persistent, bioaccumulative and toxic properties. It has been widely detected in environmental samples from various regions.	Thank you for your support.
5723 2022/10/17	European Environmental Bureau (EEB), International NGO, Belgium	The EEB supports the proposal by Belgium to identify 1,1'-[ethane-1,2-diylbisoxy] bis [2,4,6-tribromobenzene] (BTBPE) as a Substance of Very High Concern due to its vPvB properties (REACH article 57(e)). BTBPE meets the criteria for P and vP in REACH Annex XIII based on the weight of evidence assessment taking into account	Thank you for your support.

		experimental data, QSAR estimates, mesocosm studies, and detection of BTBPE in remote areas and in up to 40 years old sediment samples. BTBPE also fulfills the criteria for B and vB in REACH Annex XIII based on the weight of evidence from experimental data and mesocosm studies on bioconcentration and biomagnification in food chains. The substance is detected in wildlife in remote areas, as well as in humans and mother milk. The substance should be included in the Candidate List to prevent its use as a regrettable substitute for other brominated flame retardants.	
5739 2022/11/02	Netherlands, Member State	NL supports the proposal to include 1,1'-[ethane-1,2-diylbisoxy]bis[2,4,6-tribromobenzene] in the candidate list of SVHC in accordance with Article 57(e) of REACH, due to its very persistent and very bioaccumulative properties.	Thank you for your support.

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
5687 2022/10/17	ChemSec, International NGO, Sweden	There are a number of alternatives available on the ChemSec Marketplace: https://marketplace.chemsec.org/alternatives/chemical/37853-59-1	Thank you for the information