

Substance Name:

bis(2-ethylhexyl) tetrabromophthalate covering any of the individual isomers and/or combinations thereof

EC Number: -

CAS Number: -

**MEMBER STATE COMMITTEE SUPPORT DOCUMENT
FOR IDENTIFICATION OF**

**BIS(2-ETHYLHEXYL) TETRABROMOPHTHALATE
COVERING ANY OF THE INDIVIDUAL ISOMERS
AND/OR COMBINATIONS THEREOF**

**AS A SUBSTANCE OF VERY HIGH CONCERN BECAUSE
OF ITS vPvB (ARTICLE 57E) PROPERTIES**

Adopted on 28 November 2022

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ABBREVIATIONS

GC/MS: gas chromatography/ mass spectrometry
BFR: Brominated Flame Retardant
CCH: Compliance check
CTD: Characteristic travel distance
DecaBDE: Decabromodiphenyl ether
DEHP: bis (2-ethylhexyl) phthalate
DU: Downstream user
EC: European Commission
ECHA: European Chemicals Agency
e-MSCA: Evaluating member state competent authority
EPA: Environmental Protection Agency
FR: Flame Retardant
GM: Geometric mean
HLC: Henry's law constant
K_{oa}: Octanol:Air partition coefficient
K_{oc}: Organic Carbon Normalised Adsorption Coefficient
K_{ow}: n-Octanol:Water partition coefficient
LOD: level of detection
Log K_{ow}: Logarithmic octanol:water partition coefficient
LRTP: Long-range transport potential
NBFR: Novel brominated flame retardants
NonaBDE: Nonabromo diphenyl ether
OECD: Organisation for Economic Co-operation and Development
PBDE: Polybrominated Diphenyl Ether
PentaBDE: Pentabromo diphenyl ether
Pov: Overall persistence
(Q)SAR: Quantitative/Qualitative Structure-Activity Relationship
SVHC: substance of very high concern
TBB: Benzoic acid, 2, 3, 4, 5-tetrabromo-, 2-ethylhexyl ester
TBMEHP: Mono-(2-ethylhexyl) tetrabromophthalate
TBPH: 1, 2-Benzenedicarboxylic acid, 3, 4, 5, 6-tetrabromo-, 1, 2-bis (2-ethylhexyl) ester
TBPA-Diol: Generic designator that is used for 1, 2-Benzenedicarboxylic acid, 3, 4, 5, 6-tetrabromo-, 1-[2-(2-hydroxyethoxy) ethyl] 2-(2-hydroxypropyl) ester
ThOD: Theoretical oxygen demand
WWTP: Wastewater treatment plant

IDENTIFICATION OF A SUBSTANCE OF VERY HIGH CONCERN ON THE BASIS OF THE CRITERIA SET OUT IN REACH ARTICLE 57

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

EC number: -

CAS number: -

- The substance is identified as very persistent and very bioaccumulative (vPvB) according to Article 57 (e) of Regulation (EC) No 1907/2006 (REACH).

Summary of how the substance meets the criteria set out in Article 57 of the REACH Regulation

Bis(2-ethylhexyl) tetrabromophthalate is a diastereoisomer consisting of three stereoisomers. There is experimental information available for the whole substance, but not for the single constituents. The diastereoisomers have the same molecular formula and sequence of bonded elements and differ only in the 3D representation of the structure. That is why based on their chemical structure and in line with the PBT guidance, the three isomers are expected to behave similarly in the environment and the whole substance approach can be reasonably assumed. 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.

A weight-of-evidence determination according to the provisions of Annex XIII of REACH is used to identify the substance and its isomers as vPvB. All available relevant information (such as the results of standard tests, monitoring and modelling, and (Q)SAR results) was considered together in a weight-of-evidence approach.

Persistence:

The information available on hydrolysis is difficult to interpret considering contradicting results. However, due to its low water solubility and high K_{oc}, TBPH is expected to sorb to particles and to mainly distribute to sediment in the aquatic environment. Hydrolysis is expected to be hindered by adsorption potential of TBPH onto sediment and particulate matter. Therefore, hydrolysis is not considered to be a relevant degradation mechanism for TBPH.

AOPWIN v1.92 predicts that TBPH has an atmospheric half-life of 5.8 hours in the gas-phase and it is degraded by sunlight when dissolved in different organic solvents. However, TBPH has a very low vapour pressure, and it is predicted to distribute mainly to the particulate phase of the atmosphere. The sorbed fraction is likely to be resistant to atmospheric oxidation. This is confirmed by air monitoring data (including from remote areas), thus indicating the long-range transport potential of TBPH via air. Photodegradation in the atmosphere is therefore not considered to be a relevant removal process for TBPH.

BIOWIN predictions (low reliability) indicate that TBPH screens as potentially persistent (P) or very persistent (vP) and this is supported by screening studies where very little degradation was observed for TBPH. Furthermore, results from an inherent degradation test (reliable with restrictions) performed according to OECD guideline 302C (7% degradation in 28 days) indicate

that TBPH is persistent. It is worth noting that REACH guidance R.11 states "*Lack of degradation (<20% degradation) in an inherent biodegradability test equivalent to the OECD TG 302 series may provide sufficient information to confirm that the P-criteria are fulfilled without the need for further simulation testing for the purpose of PBT/vPvB assessment. Additionally, in specific cases it may be possible to conclude that the vP-criteria are fulfilled with this result if there is additional specific information supporting.*"

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. Many conditions (high temperature compared to EU standard conditions, pre-exposure of micro-organisms to test conditions and exposure to sunlight leading to abiotic degradation (photolysis)) 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.

Bioaccumulation:

With an experimental log K_{ow} of 10.2 TBPH screens as potentially (very) bioaccumulative according to REACH Guidance Chapter R.11 and it is not expected to be rapidly absorbed. This is confirmed by toxicokinetic studies showing that a major part of a given dose is excreted unchanged. However, a small fraction of the substance is absorbed and accumulates in tissues of the exposed organisms. This is confirmed by monitoring data which indicate an uptake of TBPH by biota.

In the available fish dietary bioaccumulation studies only a small part of the total given doses of TBPH were found in the fish at the end of the uptake period. This is probably because TBPH is poorly absorbed in the gut of the fish and not because of metabolism and excretion. No difference was detected with respect to the concentration of TBPH incubated with active or heat killed common carp (*Cyprinus carpio*) liver microsomes. Furthermore, TBPH had among studied Novel brominated flame retardants (NBFRs) the single lowest *in vitro* biotransformation rate in liver microsomes from the Blacktip grouper (*Epinephelus fasciatus*) and the lowest together, with hexabromobenzene, in liver microsomes from the Indian Ocean oriental sweetlips (*Plectorhynchus orientalis*). This also indicates that TBPH is very poorly metabolised by fish.

BMFs were measured in two of the fish dietary bioaccumulation studies (reliable with restrictions). The BMFs were of similar magnitude in both studies (0.02 for Atlantic killifish, (*Fundulus heteroclitus*) and 0.038 for rainbow trout (*Oncorhynchus mykiss*). It is important to note that the TBPH concentration in the food was very high in both studies which may have resulted in reduced bioavailability and as a consequence underestimated the BMF values. Fish BCFs were derived from data generated in the dietary study with rainbow trout using the 15 models within the OECD TG 305 BCF estimation tool and all BCFs predicted except one (method 3) were above 5000. It is worth noting that these calculated BCFs have some uncertainties

considering: a possible overestimation of the uptake rate constant (k_1) estimated by the models thus leading to an overestimation of the BCFs; a high log K_{ow} for TBPH (10.2) which is higher than the applicability domain of the 15 models; the model where a $BCF < 2000$ (method 3) was developed from data on Carp (*Cyprinus carpio*) while the applicability for other species is unknown. However, the studies indicate that TBPH is poorly metabolised with slow depuration rates (K_2 of 0.031 and 0.044) and very long half-lives in fish (15.6 and 22 days) which could become of a bioaccumulation concern once the substance has entered the food chain. Indeed, the comparison of the non-corrected depuration rate constants (K_2) from the dietary bioaccumulation studies (0.031 and 0.044) with the criteria proposed by Brooke and Crookes, 2012 (K_2 of 0.085 equals - BCF 5000 and a K_2 of 0.178 equals BCF 2000) indicates that TBPH is very bioaccumulative, i.e., has a $BCF > 5000$. A benchmark approach comparing laboratory depuration rate constants and BMF values for TBPH and substances identified as SVHC based on their vPvB properties provides further indications that TBPH has vB properties.

Other information in accordance with REACH Annex XIII points 3.2.2 (b) and (c) such as field and biomonitoring data support the above conclusion as they point towards bioaccumulation of TBPH in biota. A TMF of 2.42 for TBPH has been measured in a limnic food chain study from China, indicating trophic magnification. A TMF of 1.62 in a marine food chain study from China points in the same direction (although not statistically significant). Tentative BMFs (fish/crabs, fish/fish), although uncertain, indicate that TBPH is biomagnified in fish. In addition, a positive correlation between trophic level and TBPH concentration has been found in resident predatory birds of Korea. Finally, the ubiquitous presence of TBPH in biota (mussel, fish, birds, mammals (including in human plasma)) also in Arctic species such as ringed seal and polar bear (an endangered species) and the transfer of TBPH from human mothers to their babies via breast milk gives further indication that TBPH is very bioaccumulative.

Based on the weight-of-evidence of the data available and considering assessment information in accordance with REACH Annex XIII points 3.2.2 (a), (b) and (c), it is concluded that TBPH fulfils the vB criterion of REACH Annex XIII ($BCF > 5000$).

In conclusion:

Based on the information available, it is concluded that bis(2-ethylhexyl) tetrabromophthalate and its isomers meet the criteria for a vPvB substance in accordance with Annex XIII of the REACH Regulation, and thereby they fulfil the criteria set out in REACH Article 57 (e).

Registration dossiers submitted for the substances: Yes

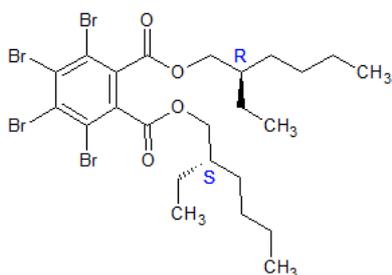
Justification

1. Identity of the substance and physical and chemical properties

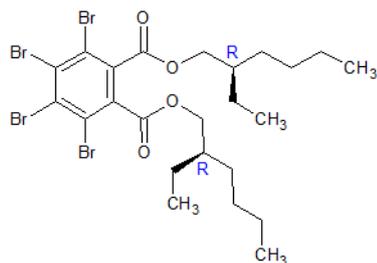
1.1 Name and other identifiers of the substances

This document addresses bis(2-ethylhexyl) tetrabromophthalate covering any of the individual isomers and/or combinations thereof

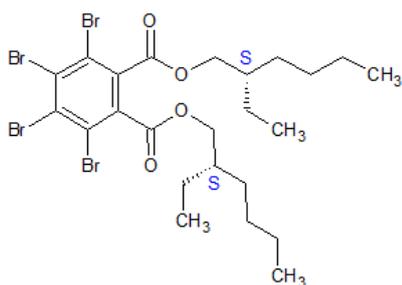
Structural formulae of the possible isomers:



(2R)-2-ethylhexyl (2S)-2-ethylhexyl tetrabromophthalate



bis[(2R)-2-ethylhexyl] tetrabromophthalate



bis[(2S)-2-ethylhexyl] tetrabromophthalate

Bis(2-ethylhexyl) tetrabromophthalate is a diastereoisomer consisting of three stereoisomers. There is experimental information available for the whole substance, but not for the single constituents. The diastereoisomers have the same molecular formula and sequence of bonded elements and differ only in the 3D representation of the structure. **Table 1** Reports the identifiers associated to the registration dossier submitted under REACH for the substance currently on the market that is a multi-constituent substance which composition includes all possible isomers.

Table 1: Substance identity

EC number:	247-426-5
EC name:	bis(2-ethylhexyl) tetrabromophthalate
CAS number (in the EC inventory):	26040-51-7
CAS number:	26040-51-7
IUPAC name:	bis(2-ethylhexyl) 3,4,5,6-tetrabromobenzene-1,2-dicarboxylate
Index number in Annex VI of the CLP Regulation	-
Molecular formula:	C ₂₄ H ₃₄ Br ₄ O ₄
Molecular weight range:	706.14 g/mol
Synonyms:	TBPH BEHTP BEH-TEBP

1.2 Composition of the substances

Name: bis(2-ethylhexyl) tetrabromophthalate

Description: Organic

Substance type: Multi-constituent

1.3 Physicochemical properties

Values for physicochemical properties were experimentally determined for the substance as a whole and not for the three individual constituents. Considering the very similar chemical structures, namely R-/R-, R-/S- or S-/S-stereoisomers of the 2-ethylhexyl chain, it is reasonable to assume that the numerical values of the phys-chem properties for the individual constituents will hardly differ.

Table 2: Overview of physicochemical properties

Property	Description of key information	Value [Unit]	Reference/source of information
Physical state at 20°C and 101.3 kPa	Experimental	Liquid at 20 °C and 101.3 kPa	Experimental study (Visual inspection) ¹
Melting/freezing point	Experimental	-27°C at 101.3 kPa (atmospheric pressure was not reported, ambient conditions are assumed)	Guideline study (DIN ISO 3016; Pour point) without detailed documentation ¹
Boiling point	Experimental	>300 °C at 1013 hPa	Guideline study (EU Method A.2 - Boiling temperature; Differential Scanning Calorimetry) without detailed documentation ¹
Vapour pressure	(Q)SAR prediction	3.56 E ⁻⁷ Pa at 25 °C	A (Q)SAR predicted vapour pressure of 3.56E ⁻⁷ Pa (at 25 °C), using MPBPWIN ²
Density	Experimental	1.541 kg/m ³ at 20 °C	Guideline study (EU Method A.3 - Relative Density; U-tube method) without detailed documentation ¹
Water solubility	Experimental	< 0.05 µg/l at 20 °C (not detectable without solubiliser) 794 µg/l at 20 °C (using 1 % acetonitrile as solubiliser)	Guideline study (EU Method A.6. – Water Solubility; Flask method), which in most parts is equivalent to OECD TG 105 ¹
Partition coefficient n-octanol/water (log value) K_{ow}	Experimental	10.2 at 25 °C	Guideline study (OECD TG 117, HPLC method) ¹
Partition coefficient organic carbon/water (log value) K_{oc}	Experimental	7.3	Guideline study (OECD TG 121, HPLC method) ¹
Partition coefficient organic carbon/air (log value) K_{OA}	(Q)SAR prediction	15.114	KOAWIN v1.10, using measured log K _{ow} (of 10.2) ²
Henry´s Law Constant (Pa m³/mol)	(Q)SAR prediction	0.00302 (bond method)	HENRYWIN v3.20 ²

¹ Registration Dossier - ECHA (europa.eu)

² EPI Suite (<http://www.epa.gov/oppt/exposure/pubs/episuite.html>)

2. Harmonised classification and labelling

There is no harmonised classification for TBPH (EC 247-426-5).

3. Environmental fate properties

3.1 Degradation

3.1.1 Abiotic degradation

3.1.1.1 Hydrolysis

The software HYDROWIN v2.00³ estimates the hydrolysis half-life of TBPH to 29 days at pH 7 and 2.9 days at pH 8. However, the tetrabromophenyl and 2-ethylhexyl fragments of TBPH are not available in the HYDROWIN fragment library or otherwise cannot be considered by the software (ortho position fragments not considered) and are instead replaced by the tribromophenyl and isobutyl fragments, respectively. Since these substitute fragments would result in less steric hinderance of the hydrolysis reaction, the predicted hydrolysis half-life, using HYDROWIN, will therefore likely be underestimated. In addition, TBPH has a very low water solubility.

The hydrolytic stability of TBPH has been studied in a study performed according to OECD test guideline 111, available in the registration dossier⁴. The water solubility of TBPH is < 0.05 µg TBPH/L and therefore an aqueous solution with 1% acetonitrile of 0.4 mg TBPH/L was used (TBPH solubility in 1% acetonitrile solution is 794 µg TBPH/L). Only the preliminary phase of the study, where the hydrolysis at pH 4, 7 and 9 at 50 °C is determined, was performed. The disappearance of the test item was > 91% after the study period at each pH. The resulting half-lives were 30.4 hours at pH 4, 44.1 hours at pH 7 and 77.5 hours at pH 9. The registrant used the van 't Hoff equation to extrapolate the half-lives to a temperature of 20°C, which gave the following values: 10.1 days at pH 4, 14.7 days at pH 7 and 25.8 days at pH 9. One transformation product, tetrabromophthalic acid, was identified but not quantified. The identification of the metabolite was performed in a second experiment performed at 60°C and pH 4. The registrant has given this study reliability 1. The registrant concludes that TBPH is rapidly hydrolysed in the environment and therefore not fulfils the P/vP criteria of REACH. It is worth noting that according to the PBT guidance (REACH Chapter R.11 (ECHA, 2017a)) 'the degradation half-lives obtained in a hydrolysis test cannot be compared to the persistence criteria of Annex XIII'. Furthermore, this study was only a preliminary study that should have been followed up by a definitive study, performed with at least three different temperatures according to the guideline. It is therefore considered unreliable.

In contrast to the hydrolysis study referred to in the previous paragraph, Environment and Climate Change Canada, Health Canada (2019) in their evaluation of TBPH refers to an unpublished industry hydrolysis study (not available) of a commercial mixture of TBB and TBPH performed according to the criteria stated within the test method (92/69/EEC C7) that the hydrolysis half-life of TBPH was concluded > 1 year at each pH value (4, 7 and 9) and 25°C.

In addition, DEHP (the unbrominated skeleton of TBPH) is reported to have a hydrolysis half-life > 2000 years according to the fact sheet on ECHAs dissemination web page⁵. While read across may not be possible, this indicates that the hydrolysis of TBPH may not be rapid.

³ EPI Suite (<http://www.epa.gov/oppt/exposure/pubs/episuitel.htm>)

⁴ Registration Dossier - ECHA (europa.eu)

⁵ [Registration Dossier - ECHA \(europa.eu\)](http://europa.eu)

3.1.1.3 Phototransformation/photolysis

No information on phototransformation in air, water or soil is included in the registration dossier⁶.

Davis and Stapleton (2009) studied the photodegradation of nonabrominated diphenyl ethers, 2- ethyl hexyltetrabromobenzoate (TBB) and TBPH. The substances dissolved in either toluene, methanol or tetrahydrofuran, were added to glass vials which were exposed to sunlight in the summer and early fall of 2008. The study took place in Durham, North Carolina and the average solar radiation during the test period was 687.5 W/m². Three vials were sampled after 5, 15, 30, 60 and 240 minutes of sunlight exposure. The half-life for TBPH was 147 minutes in toluene, 220 minutes in methanol and 168 minutes in tetrahydrofuran. The calculated degradation rates for TBPH were slower than those for decaBDE (substance identified as **PBT/vPvB**) and the nonaDBE congeners included in the study across all solvents. The authors report that three tribrominated and two dibrominated isomers appeared to have been formed through the degradation of TBPH.

3.1.1.3.1 Phototransformation in air

No information on phototransformation in air is included in the registration dossier.

The software AOPWIN v1.92⁷ estimates the half-life for atmospheric oxidation in the gas-phase to 5.9 hours. However, the model predicts that ≥99.8% will be sorbed to airborne particulates and that the sorbed fraction may be resistant to atmospheric oxidation. Because the sorbed fraction is likely to be resistant to atmospheric oxidation, the AOPWIN half-life value based on reaction with hydroxyl radicals in the gas-phase is most probably an underestimation of the half-life in air. The sorbed fraction to particulates may increase its residence time and potential for long-range transport in air.

Considering the very low vapour pressure (3.56 E-7 Pa at 25 °C (estimated value, MPBPWIN v1.43⁷)), photolysis in the atmosphere is not considered to be a relevant degradation pathway. However, TBPH has frequently been detected in air also in remote areas. In most cases detectable only in the particulate phase of the air samples. Thus, supporting that the sorbed fraction is likely to be resistant to atmospheric oxidation.

3.1.1.3.2 Phototransformation in water

No information on phototransformation in water is included in the registration dossier.

3.1.1.3.3 Phototransformation in soil

No information on phototransformation in soil is included in the registration dossier.

3.1.1.4 Summary on abiotic degradation

It is not possible to conclude on hydrolysis of TBPH based on the available data. However, due to its low water solubility and high K_{oc} TBPH will be sorbed to particles and mainly distributed to sediment in the aquatic environment and hydrolysis is therefore not considered to be a relevant degradation mechanism for TBPH.

⁶ [Registration Dossier - ECHA \(europa.eu\)](http://europa.eu)

⁷ EPI Suite (<http://www.epa.gov/oppt/exposure/pubs/episuitedi.htm>)

The available information indicates that TBPH can be photolytically degraded in the gas-phase of air. However, TBPH has a very low vapour pressure and based on monitoring data and model predictions it is mainly distributed to the particulate phase of the atmosphere. The sorbed fraction is likely to be resistant to atmospheric oxidation. Photodegradation in the atmosphere is therefore not considered to be a relevant removal process for TBPH.

3.1.2 Biodegradation

3.1.2.1 Biodegradation in aqueous media or aqueous environment

3.1.2.1.1 Estimated data

The software BIOWIN v4.10⁸ gives the following predictions for TBPH:

BIOWIN 2: 0.1319 (<0.5)	→ Does not biodegrade fast;
BIOWIN 3: 1.9718 (<2.25)	→ Ultimate biodegradation longer than months;
BIOWIN 6: 0.0945 (<0.5)	→ Not readily degradable.

According to the REACH guidance R.11 (ECHA, 2017a) these BIOWIN predictions indicate that TBPH is potentially persistent or very persistent. However, the reliability of these predictions is unclear since six linear/branched C-atoms are not accounted for by BIOWIN 2 and 3.

3.1.2.1.2 Screening tests

The registration dossier contains no ready biodegradation studies. However, the USEPA lists results from two ready biodegradation studies on TBPH in an assessment of alternatives to pentabromodiphenyl ether (PentaBDE) (USEPA, 2015). One study conducted according to OECD TG 301D gave less than < 4 % ThOD after 10 days. The other study, a closed bottle test (OECD 301B) gave 2 % degradation as measured by CO₂ production after 28 days. These studies were not accessible and no details on the studies are given in the report, but the USEPA considers both to be "Adequate guideline studies".

The registration dossier includes one inherent biodegradability test according to OECD guideline 302 C (Modified MITI test). A mixture of activated sludge from two different wastewater treatment plants treating predominantly domestic wastewater and activated sludge from a wastewater treatment plant (WWTP) treating predominantly industrial wastewater was used as inoculum. The three sludge types were mixed taking 2 parts from each of the two domestic WWTPs plus 1 part from the industrial WWTP. (Addition of 20 % sludge from an industrial wastewater plant may have made the conditions for degradation more favourable than if only domestic sludge had been used). Continuously stirred 250 ml closed flask (three replicates) were incubated for 28 days in the dark at 25 ± 2°C. The concentration of inoculum was 100 mg /L and the TBPH concentration was 30 mg/L. A control (inoculum only), and a positive control (sodium benzoate) were run in parallel. The biodegradation was estimated by measuring the O₂ consumption. The degradation of TBPH was 6 % after 7 days and 7 % after 28 days. The degradation of the reference compound sodium benzoate reached 65 % after 7 days but remained 2 % below the level of ≥ 65 % after 14 days. This is according to the authors caused by high activity of the sludge in the blank control. Despite this the test is considered to be reliable with restrictions and TBPH concluded to be persistent.

TBPH is based on the above considered to be not readily/inherently biodegradable and thus persistent (P) and potentially very persistent (vP).

⁸ EPI Suite (<http://www.epa.gov/oppt/exposure/pubs/episuitedl.htm>)

3.1.2.1.3 Simulation tests

3.1.2.1.3.1 Biodegradation in water

Not available.

3.1.2.1.3.2 Biodegradation in sediment

De Jourdan *et al* (2013) studied the fate of four novel brominated flame retardants, bis(tribromophenoxy)ethane (BTBPE), tetrabromobisphenol A bis(2,3-dibromopropyl ether (TBBPA-DBPE), TBPH and 2-ethylhexyl-2,3,4,5-tetrabromobenzoate (TBB) in an outdoor mesocosm study. The study was performed at The Guelph Turfgrass Institute in Ontario Canada, that has a climate comparable to the northern parts of the European continent. The mean air temperature in this area of Canada is normally around 22°C in July, 21°C in August and 15°C in September. The mesocosms had a depth of 1.2 m, a diameter of 3.9 m and were filled with water to approximately 1 m (ca 12000 L). The water supply for the mesocosms was an irrigation pond (62 x 62 x 4 m deep) supplied by a well located on site.. Artificial sediment containing organics-rich soil (1:1:1 mixture of topsoil:manure:compost, Waterdown Garden Supply, Troy, ON, Canada) with an organic content of 11.6% dry total C (1.6% dry inorganic C, and 10.0% dry organic C) was placed on trays 52.1 x 25.4 x 5.7 cm that were placed on the bottom of each mesocosm so that > 50% of bottom surface was covered.

The fate study took place over two years, with year 1 serving for method development purposes. The mesocosms were established in May 2008, and treated in July 2008. Before treatment water was circulated from the irrigation pond into all mesocosms for three weeks at a flow rate of approximately 12 m³ per 24 h to decrease heterogeneity of water chemistry, zooplankton, and algal assemblages. Circulation was discontinued on June 25, one week prior to treatment. Measured water quality parameters in the mesocosm water during the study period (16 July – 24 September 2009) is presented in **Table 3**. With regards to pH, information on pH can be obtained from another publication that used the same mesocosm (including the same source of water and the same artificial sediment) for a bioaccumulation study in 2008 – de Jourdan *et al* 2014. This shows a pH range of 7-9 with average values being 8.7±0.6 (n=30).

Table 3: Arithmetic means of water quality parameters (16 July – 24 September 2009) in ponds used in the mesocosm study by de Jourdan *et al.*, 2013 (additional information provided by the author).

	Temp (°C)	DO (mg/l)	Alkalinity (mg HCO ₃ ⁻ /L)	Hardness (mg CaCO ₃ /L)	Conductivity (µS/cm)
Pond 3	19.7	8.6	145	186.6	583
Pond 12	19.2	8.4	142.5	198.7	571

In year 1, Firemaster® BZ-54 (TBPH:TBB 1:4) was applied to the water phase of three mesocosms by subsurface injection. The simultaneous application of TBPH and TBB is not expected to have affected the results of this study. Five injections of 25 ml of commercial BZ-54, dissolved in 125 ml dimethylsulfoxide were made at several locations in the mesocosms. The aim was to achieve homogeneous distribution of the compound at a nominal concentration of 0.03 mg/L, (which is at least one order of magnitude above the water solubility of < 0.05 µg/L), to achieve a target concentration of 500 ng TBPH/g sediment in the upper 5 cm on partitioning into the sediment, which is consistent with concentrations observed in sewage sludge from the San Francisco Bay area.

In Year 2 (July 16, 2009), two mesocosms from each treatment were retreated at the same concentration, but no additional water was added.

Sediment samples were collected in triplicate during July to September 2009, days 1, 4, 7, 14, 28, 42 and 70 after the treatment 16 July year 2. The samples were collected using copper tubes (100 mm length, 15 mm internal diameter) to core the upper 3 cm of the sediment. Separate sediment trays (33 x 18 x 10cm) with floats attached by rope were deployed for

sediment sampling, because they could be raised to the surface for sample collection with minimal risk of disturbance and resuspension of sediments. On sampling days, two sediment samples were collected from one sediment tray, and the third sample was collected from a tray on the opposite side of the mesocosm. Water-column samples (4 L) for various analyses were collected on days 1, 4, 7, 14, 28, 42, and 70 using a depth integrated water column sampler. Aliquots were transferred to a 1-L amber glass bottle for residue analysis of NBFR, and the remaining water was used to measure other water chemistry parameters.

The identification and quantification of the NBFRs were performed using a GC/MS operated in the electron capture negative ionisation mode. TBPH was monitored using the characteristic mass fragment at m/z 464 and was quantified by monitoring the bromine ion (m/z 79 and 81). Full-scan mass spectra (m/z 60–800) were also recorded for each sample using electron-capture negative-ion mode. Selected samples were also run in full-scan electron ionisation (EI) mode to elucidate further the structures of degradation products.

The authors reported that standards of PBDEs were analysed by the same method to determine whether any of the observed peaks in the samples were due to field or laboratory contamination with PBDE congeners. The stock solution and technical products used to treat the mesocosms were evaluated for impurities. Matrix spikes were performed by adding 200 ml of the test compounds at a concentration of 100 ng/ml to the diatomaceous earth prior to extraction. The recovery (which is particularly important for biodegradable compounds) and breakdown of the compounds throughout the experiment were assessed and modifications to the method (i.e., reduced acidification of the silica gel) were made to maximise recovery and minimise degradation. The mean recovery rate of the analysis method was 77.4 % (range 60%–88%), with a standard deviation of 5.9 %. It is noted that according to OECD TG 308, the recovery immediately after the addition of the test substance to the test system should range from 70% to 110% for non-labelled substances. Hence, as the lowest recoveries of the method were below 70%, the measured concentrations of TBPH might have been slightly underestimated in the study.

Method (pre-ASE (Accelerated Solvent Extraction)) and procedural (post-ASE) blanks were run with every batch of samples (8–10) and were extracted in a manner identical to that of the samples. The analysis showed that the test compounds were not detected in the laboratory nor in the method blanks.

There were large fluctuations in TBPH concentration in the particulate matter throughout the study and the data did not fit first-order kinetics very well, with an r^2 value of 0.06. The DT_{50} in the particulate matter was estimated to 25 days with a 95% CI of 7–44 days. The r^2 was 0.06 and the p value 0.481. However, some degradation may have occurred in the particulate matter. There was one major unknown peak in the chromatogram which agreed fairly well with the expected mass of a tribrominated anhydride. This could have been formed via hydrolysis of the ester groups to tetrabromo phthalic acid subsequently forming an anhydride. The authors speculate that this could be due to photolysis in the particulate compartment as debrominated analogues of TBPH were detected in a photolysis study by Davis and Stapleton (2009), see paragraph on photolysis above.

The concentration in the sediment did not fluctuate in the same manner with the maximum concentration being almost equal to the mean concentration during the whole sampling period (**Table 4**). For the sediment, the regression equations were not significant, suggesting no significant decline. The authors of the study report the result as $DT_{50} > 200$ days for the sediment phase. The actual DT_{50} estimation (regression analysis) gave a value of 9303 days with a 95% confidence interval of 1330 - 17280 days.

The sediment used in this study was not a natural sediment and thus the representativeness to natural sediment/microorganism community is uncertain. It would have been preferable to use a natural sediment instead of creating an artificial one. However, there was a more than 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. 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 DT₅₀ may represent a worst-case scenario.

Contrary to this, many other conditions may have favoured dissipation/degradation:

- The average dissolved oxygen content in the water during the study was around 8.5 mg/l (de Jourdan pers.com). Thus, there were probably no issues anaerobicity in the upper layer of the artificial sediment-

- **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 the mean temperature in the mesocosms during the study was around 19 °C (de Jourdan pers. com). Thus the average temperature during the study period was 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 were exposed to sunlight (as well as wind and rain) which could favour/lead to dissipation from the mesocosm.

Despite these probably 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 (**Table 4**). Furthermore, no degradation products were identified in the sediment.

Table 4: Concentrations of TBPH (µg/kg OC) during the study period in sediments in ponds used in the mesocosm study by de Jourdan *et al.*, 2013.

	TBPH concentration in the sediment (µg/kg OC)				
	Max	Arithmetic mean	Median	Geometric mean	Time weighted average
Pond 3	32.6	32.6	32.6	32.6	32.5
Pond 12	36.8	34.6	34.2	34.6	35.3

Regardless of whether this study is representative of a natural sediment the results from this study should be treated with care as a number of physical, experimental and analytical factors (e.g., sediment-to-water diffusion and resuspension, inhomogeneous distribution in the mesocosms, matrix interference) likely contributed to the level of uncertainty in determining the exact value of the dissipation times. The study is therefore considered to be reliable with restrictions. However, it can be concluded that TBPH was very persistent in the sediment of this test system with a DT₅₀ > 200 days. Also, the slow disappearance from the particulate compartment of the water phase DissT₅₀= 50 days (median) (95% C.I 14-**86 days**) (recalculated to 12° C from a mean temperature around 19 °C) may indicate that TBPH is very persistent. This DissT₅₀ is however very uncertain as the concentration of TBPH in the particulate matter fluctuated greatly.

3.1.2.2 Biodegradation in soil

3.1.2.2.1 Simulation tests in soil

Not available.

3.1.2.3 Summary and discussion on biodegradation

BIOWIN predictions (BIOWIN 2, 3, 6) with a low reliability, indicate that TBPH screens as potentially persistent or very persistent to biodegradation. This is supported by two ready biodegradation tests referred to by the USEPA (2015) which show that TBPH is not readily biodegradable (< 4% degradation). This is confirmed by the results from an inherent degradation test (reliable with restrictions) performed according to OECD guideline 302C at 25°C, which gave 7% degradation in 28 days despite that the conditions may have been more favourable than proposed in the guideline. According to REACH guidance R.11 (ECHA, 2017a) a "*Lack of degradation (<20% degradation) in an inherent biodegradability test equivalent to the OECD TG 302 series may provide sufficient information to confirm that the P-criteria are fulfilled without the need for further simulation testing for the purpose of PBT/vPvB assessment. Additionally, in specific cases it may be possible to conclude that the vP-criteria are fulfilled with this result if there is additional specific information supporting.*"

In addition to the screening studies de Jourdan *et al.* (2013) reports a sediment DT₅₀ > 200 days for TBPH from an outdoor mesocosm study thus indicating that TBPH may be very persistent in sediment. However, 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 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. Many conditions (high temperature compared to EU standard conditions, pre-exposure of microorganisms to test conditions and exposure to sunlight leading to abiotic degradation (photolysis)) 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. The result from this study goes well in line with the other available evidence and adds to the weight of evidence indicating that TBPH fulfils the vP criterion of REACH Annex XIII.

3.1.3 Field data

See information in section 3.3.2

3.1.4 Degradation data on structural analogues

Only very limited degradation data is available for structurally similar substances.

There are two other brominated phthalates registered in REACH, 2-(2-hydroxyethoxy)ethyl 2-hydroxypropyl 3,4,5,6-tetrabromophthalate (**TBPA-Diol**) (EC 243-885-0)⁹ and **reaction products of tetrabromophthalic anhydride with 2,2'-oxydiethanol and methyloxirane** (TBPA Diol (mixed esters)) (EC 616-436-5)¹⁰.

TBPA-Diol is registered at 1-10 tpa and there are no data in the dossier.

TBPA Diol (mixed esters) is a UVCB that contains constituents that are structurally similar to TBPH. It is registered at 100 – 1000 tpa but the dossier contains no experimental data. ECHA

⁹Registration Dossier - ECHA (europa.eu)

¹⁰ Registration Dossier - ECHA (europa.eu)

performed a CCH with 15 data requests including a simulation test. The deadline for delivering the data was June 2022.

Tetrabromophthalic anhydride (EC 211-185-4)¹¹, theoretically a metabolite of TBPH, is also registered under REACH at 100-1000 tpa. For this substance, the registration dossier contains a soil study from 1979. The study reports hydrolysis of the anhydride to tetrabromophthalic acid but no biodegradation over 28 days.

For 2-ethylhexyl 2,3,4,5-tetrabromobenzoate (TBB), which is not registered in the EU, there are some data available. TBB is used together with TBPH in flame retardant formulations such as Firemaster® 500. Photolysis studies shows that TBPH is more stable than TBB (Davis and Stapleton, 2009). TBB was also included in the mesocosm study by de Jourdan *et al.* (2013). TBB had a shorter DT₅₀ in the particulate matter than TBPH, 9 days compared to 25 days for TBPH. In sediment where TBPH had a DT₅₀ > 200 days TBB was not detectable despite being applied at least at a 4 times higher dose than TBPH.

3.1.5 Summary and discussion of degradation

A hydrolysis study sponsored by the registrant reports a DT₅₀ of 14.7 days for TBPH in a 1% acetonitrile solution at pH7 and 20 °C extrapolated from 50 °C with van 't Hoff's equation. This study was however only the preliminary part of an OECD guideline 111 study and is therefore not considered fully reliable. Furthermore, contradictory to this, a hydrolysis half-life > 1 year at pH 4, 7 and 9 is reported by Canadian authorities in their evaluation of TBPH (Environment and Climate Change Canada, Health Canada 2019). In addition, the structural analogue DEHP (the unbrominated skeleton of TBPH) is reported to have a hydrolysis half-life > 2000 years according to the fact sheet on ECHAs dissemination web page. While read-across may not be possible, this indicates that the hydrolysis of TBPH may not be rapid.

In addition, due to its low water solubility and high K_{oc} TBPH will be sorbed to particles and mainly distributed to sediment in the aquatic environment (cf. Table 5). Hydrolysis is expected to be hindered by adsorption potential of TBPH onto sediment and particulate matter. Mackay Level III distribution modelling predicts that only ca. 2 % of TBPH will be distributed to water and 98% to sediment when all emissions are assumed to be to water compartment (see **Table 5**). Hydrolysis is therefore not considered to be a relevant degradation mechanism for TBPH.

The available information indicates that TBPH can be photolytically degraded in the gas-phase of the atmosphere. However, TBPH has a very low vapour pressure and is not expected to distribute significantly to the gas phase of the atmosphere, which is confirmed by the frequent findings of the substance in the particulate phase of the atmosphere, including in remote areas. Photodegradation in the atmosphere is therefore not considered to be a relevant removal process for TBPH.

BIOWIN predictions indicate that TBPH screens as persistent or very persistent to biodegradation, but the reliability of these predictions is unclear. Two ready biodegradation tests referred to by the USEPA (2015) show that TBPH is not readily biodegradable (< 4 % degradation). This is confirmed by the results of an inherent degradation test performed according to OECD guideline 302C at 25°C, which gave 7% degradation in 28 days despite that the conditions may have been more favourable than proposed in the guideline.

REACH guidance R11 states "*Lack of degradation (< 20 % degradation) in an inherent biodegradability test equivalent to the OECD TG 302 series may provide sufficient information to confirm that the P-criteria are fulfilled without the need for further simulation testing for the*

¹¹ [Registration Dossier - ECHA \(europa.eu\)](https://echa.europa.eu)

purpose of PBT/vPvB assessment. Additionally, in specific cases it may be possible to conclude that the vP-criteria are fulfilled with this result if there is additional specific information supporting."

No simulation study is available for TBPH. In addition to the screening studies presented above, de Jourdan *et al.* (2013) reports a sediment $DT_{50} > 200$ days from an outdoor mesocosm. 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. Many conditions (high temperature compared to EU standard conditions, pre-exposure of micro-organisms to test conditions and exposure to sunlight leading to abiotic degradation (photolysis)) 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 used in this test system. This goes well in line with the other available evidence and adds to the weight of evidence indicating that TBPH fulfils the vP criterion of REACH Annex XIII.

There is very limited information available for other brominated phthalates or similar substances. Tetrabromophthalic anhydride (EC 211-185-4), a theoretical degradation product of TBPH, appears to be persistent. The registration dossier for this substance contains results from a soil study from 1979 (ECHA dissemination site, 2021). This study reports hydrolysis of the anhydride to tetrabromophthalic acid but no further biodegradation over 28 days.

TBPH has been detected in all compartments of the environment including air, surface water, sediment mostly in urban areas (see section 3.2.4). TBPH is present also in remote areas without known local sources (see section 3.3.2). It has been detected in the particulate phase of air in e.g., the East Greenland Sea, Svalbard, the Tibetan plateau and the Canadian Arctic (Möller *et al* 2011a, Salamova *et al* 2014, Xiao *et al* 2012). TBPH has also been detected in water samples taken in the East Greenland Sea, although in very low concentrations (Möller *et al* 2011a). Besides showing that TBPH has a potential for long-range transport, the detection of TBPH in air and water in remote areas without known local sources adds to the evidence that TBPH is very persistent.

Overall, based on the available information and a weight-of-evidence approach, it is concluded that TBPH fulfils the very persistent criterion (vP) set out in REACH Annex XIII.

3.2 Environmental distribution

3.2.1 Adsorption/desorption

TBPH has a low water solubility ($< 0.05 \mu\text{g/l}$ at $20 \text{ }^\circ\text{C}$) and a high $\log K_{oc}$ (7.3).

The low water solubility and the high $\log K_{oc}$ indicate that TBPH is highly adsorptive and therefore likely to partition to soil and in the aquatic environments to suspended matter and sediment.

3.2.2 Volatilisation

The tendency for TBPH to volatilise from water to air is considered to be low based on the predicted value of Henry's law constant (HLC) of $0.003 \text{ Pa m}^3/\text{mol}$. The HLC for TBPH is far below the HLC-trigger of $250 \text{ Pa m}^3/\text{mol}$ given in the REACH guidance R.16 (ECHA, 2016) for volatile substances. It is also far below the $1\text{-}10 \text{ Pa m}^3/\text{mol}$ indicated in the OECD guidance document on aquatic toxicity testing of difficult substances and mixtures (OECD, 2019) used as a threshold for substances that can significantly volatilise during vigorous mixing conditions

where the opportunity for water/air exchange is high. It is even far below the indicator value of difficulties of $>0.1 \text{ Pa m}^3/\text{mol}$ for HLC for test solution preparation and testing in the same OECD guidance (OECD, 2019).

TBPH is, based upon the low Henry's law constant and the low vapour pressure, expected to have a low potential for volatilisation to the atmosphere.

3.2.3 Distribution modelling

When run with equal emissions to air, water and soil, the EPI Suite Fugacity Level III model predicts that TBPH is mainly distributed to soil and sediment. This is the case also when the model is run with emissions only to air or water (see **Table 5**).

Table 5: EPI Suite Fugacity level III output (EQC default) for TBPH (using the values for physical/chemical properties calculated by EPI Suite)

	Mass amount (%)	Emissions (kg/h)
<i>Equal emissions to air, water, and soil</i>		
Air	0.0654	1000
Water	1.3	1000
Soil	34.2	1000
Sediment	64.4	0
<i>Emissions to air only</i>		
Air	0.7	1000
Water	0.4	0
Soil	78.5	0
Sediment	20.4	0
<i>Emissions to water only</i>		
Air	1.1×10^{-10}	0
Water	1.98	1000
Soil	1.2×10^{-8}	0
Sediment	98	0
<i>Emissions to soil only</i>		
Air	0	0
Water	0	0
Soil	100	1000
Sediment	0	

Based on the modelled removal TBPH will mainly be removed to sludge in a WWTP due to its high K_{oc} and low biodegradation potential (see **Table 6**).

Table 6: Modelled removal of TBPH in WWTP that uses activated sludge secondary treatment (STPWIN model of EPI Suite (v4.11))

	Removal (%)
Total removal	94.04
Total biodegradation	0.78
Total sludge adsorption	93.26
Total to air	0.00

3.2.4 Field data

Monitoring data for TBPH in air, water, sediment, soil, WWTP sludge, landfill leachate and biota are reported in section 3.3.2 and in "Annex I – Environmental and human monitoring data".

TBPH has been found in European air (at concentrations up to $7.1 \text{ pg TBPH}/\text{m}^3$ in Norway), water (at concentrations up to $1.29 \text{ pg TBPH}/\text{L}$ in East Greenland Sea), and sediment (up to $3.3 \text{ }\mu\text{g}$

TBPH/kg dw. in Sweden close to a WWTP outlet). It has also been found in European biota such as in invertebrates (at concentrations up to 0.175 µg TBPH/kg ww in blue mussels in Norway), fish (at concentrations up to 1.31 µg TBPH/kg ww in whole capelin in Svalbard), birds (at concentrations up to 3.75 µg TBPH/kg ww in livers of common eider in Svalbard) and in mammals (at concentrations up to 0.88 µg TBPH/kg ww in livers of ringed seal in Svalbard).

3.2.5 Summary and discussion of environmental distribution

TBPH is strongly hydrophobic with a low water solubility (< 0.05 µg/L), a high log K_{ow} (10.2) and a high log K_{oc} (7.3).

Distribution modelling indicate that TBPH mainly is distributed to the soil and sediment compartments when released to the environment. If released to water the vast majority of TBPH would end up in the sediment, with a small fraction associated with the pelagic compartment (suspended matter and biota). Removal of TBPH during WWTP processes is estimated to mainly be via adsorption to sludge (94%).

Based upon the low vapour pressure and the low Henry's law constant TBPH is expected to have a low potential for volatilisation to the atmosphere. However, concentrations of TBPH found in air from remote locations suggests that atmospheric transport is occurring (mainly via the particulate phase). Monitoring data indicate that TBPH can be found in the gas and particulate phase of the atmosphere (Möller *et al.*, 2011b; Li *et al.*, 2016).

TBPH have been detected in European air, water, sediment, and biota.

3.3 Data indicating potential for long-range transport

3.3.1 Modelling data

The predicted atmospheric half-life for TBPH using AOPWIN v1.92 is estimated to be 5.9 hours in the gas-phase, but the model also predicts that ≥99.8% will be sorbed to airborne particulates and that the sorbed fraction may be resistant to atmospheric oxidation. The AOPWIN half-life value based on reaction with hydroxyl radicals in the gas-phase is therefore most probably an underestimation of the half-life of TBPH in air as the fraction of TBPH sorbed to particulates may increase its residence time and potential for atmospheric long-range transport. This is confirmed by monitoring data in remote areas far away from point sources (see section 3.3.2).

Environment and Climate Change Canada, Health Canada (2019) estimated the characteristic travel distance (CTD) to be 2850 km using the OECD P_{ov} and LRTP Screening Tool (Wengman *et al.*, 2009) in their evaluation of TBPH. However, considering the uncertainty on half-lives in air, water and soil described above, which are used as input values in the screening tool, the interpretation of what the estimated CTD represents is unclear.

3.3.2 Monitoring data

3.3.2.1 Concentrations in air

Several publications report findings of TBPH in air in remote locations despite its low vapour pressure.

Möller *et al.* (2011a) investigated in 2009 the spatial distribution of polybrominated diphenyl ethers (PBDEs) and several alternative non-PBDEs in air and seawater in the East Greenland Sea. TBPH was not detected in the gas phase but in the particulate phase with concentrations ranging from n.d. to 0.08 pg TBPH/m³. The detection frequency was 40%.

Möller *et al.* (2011b) analysed the occurrence of brominated flame retardant including TBPH in marine boundary layer air during a polar expedition from the East China Sea to the High Arctic. TBPH was detected in 24% of the gas phase samples and 25 % of the particle samples. The measured concentration of TBPH in gas phase and particle samples were 0.43 ± 0.88 pg TBPH/m³ and 0.13 ± 0.12 pg TBPH/m³, respectively. These results differ from other studies in that TBPH was found in higher concentrations in the gas phase as compared to the particle phase.

During a sampling cruise from the East Indian Archipelago toward the Indian Ocean and further to the Southern Ocean (November 2010 to March 2011) Möller *et al.* (2012) investigated the occurrence, distribution, and temperature dependence in the marine atmosphere of several alternative brominated flame retardants (BFRs) including TBPH. TBPH was detected in 90% of the samples (n = 20) and only in the particulate phase. The concentrations ranged from not detected to 2.8 pg TBPH/m³. There was no clear distribution pattern.

Xiao *et al.* (2012), monitored atmospheric concentrations of halogenated flame retardants for approximately one year at two remote stations, Nam Co on the Tibetan Plateau (n=15) and Alert in the Canadian High Arctic (n = 14). The average air (gas + particle) TBPH concentrations at Alert and Nam Co were 0.80 and 0.38 pg TBPH/m³, respectively. The ranges at both sites were similar, in the magnitude of 0.1-1.5 pg TBPH/m³. TBPH was detected above the blank and the above the method detection limit 13/14 and 3/14, respectively at the Alert and at 15/15 and 8/15, respectively at Nam Co.

Salamova *et al.* (2014) measured TBPH in the particle phase of atmospheric samples (n = 34) collected at Longyearbyen on Svalbard from September 2012 to May 2013. The detection frequency was 88%, the mean concentration was 2.7 ± 0.49 pg TBPH/m³ (range 0.27-14 pg/m³).

Yu *et al.* (2015) collected air samples at Little Fox Lake in Canada's Yukon Territory from August 2011 to December 2014. TBPH was detectable at 38% of the samples with an average concentration of 0.86 pg TBPH/m³.

3.3.3.2 Concentrations in water

TBPH has been detected in water in remote locations, despite its low water solubility.

Möller *et al.* (2011a) detected TBPH in the dissolved phase of 25% of the water samples taken in the East Greenland Sea in 2009. The concentrations ranged from non-detect to 1.3 pg TBPH/L. The detection rate in the particulate phase was 6% with concentrations ranging from n.d. to 0.12 pg TBPH/L.

TBPH was, during a polar expedition from the east China sea to the Arctic, detected at one station (in the dissolved phase) with a concentration of 0.2 pg TBPH/L (Möller *et al.*, 2011b).

3.3.3.3 Concentrations in biota

TBPH has been detected in biota in the Arctic.

Sagerup *et al.* (2010), analysed 14 brominated flame retardants including TBPH in the Norwegian Arctic (Svalbard) 2007 - 2009. The sampled species were: capelin (*Mallotus villosus*), common eider (*Somateria mollissima*), black-legged kittiwake (*Rissa tridactyla*), Brünnich's guillemot (*Uria lomvia*), ringed seal (*Phoca hispida*), arctic fox (*Vulpes lagopus*), and polar bear (*Ursus maritimus*). TBPH was detected in capelins, eiders, guillemots, kittiwakes and ringed seal but not in arctic fox and polar bear (see **Table 7**).

Table 7. Concentration of TBPH in species from the Norwegian Arctic 2007-2009 (Sagerup et al., 2010)

Species	n	Lipid (%)	Detection frequency (%)	Concentration ($\mu\text{g TBPH/kg ww}$) Arithm. mean \pm standard deviation, (range)
Fish				
Capelin (<i>Mallotus villosus</i>) -Whole body	10	2.6	90	0.72 \pm 0.29, (<0.12 - 1.31)
Birds				
Brünnich's guillemot (<i>Uria lomvia</i>) -egg	10	11.0	70	1.8 \pm 1.36, (<0.11 - 3.4)
Common eider (<i>Somateria mollissima</i>) -liver	10	3.7	60	1.65 \pm 1.40, (<0.14 - 3.75)
Kittiwake (<i>Rissa tridactyla</i>) -liver	10	5.5	50	0.8 \pm 0.36, (<0.17 - 1.4)
Mammals				
Arctic fox (<i>Vulpes lagopus</i>) -liver	10	7.1	0	(<0.14)
Polar bear (<i>Ursus maritimus</i>) -plasma	10	0.9	0	(<0.292)
Ringed seal (<i>Phoca hispida</i>) -liver	10	3.5	60	0.57 \pm 0.2, (<0.14 - 0.88)

KLIF (2013) reports measurements of TBPH from a screening study which includes measurements performed in the arctic (Svalbard). It is notable that the detection frequency was 100% for kittiwake eggs and 95% for polar Bear plasma from Svalbard (see **Table 8**). The

authors also measured TBPH in species in mainland Norway, which is further presented in Annex I.

Table 8. Concentrations of TBPH in species from the Norwegian Arctic 2010 - 2012 (KLIF, 2013)

Species	n	Lipid (%)	Detection frequency (%)	Concentration ($\mu\text{g TBPH/kg ww}$) Arithm. mean \pm standard deviation, (range)
Fish				
Atlantic cod (<i>Gadus morhua</i>) -liver	10	51	10	0.017* \pm 0.01* (<0.013 - 0.07)
Polar cod (<i>Gadus morhua</i>) -whole body (pooled)	10	1.72	0	<0.01
Birds				
Common eider (<i>Somateria mollissima</i>) -egg	12	17	58	0.04* \pm 0.06*, (<0.01 - 0.21)
Glaucous gull (<i>Larus hyperboreus</i>) -plasma	12	n.d.	17	0.009* \pm 0.010*, (<0.01 - 0.03)
Kittiwake (<i>Rissa tridactyla</i>) -egg	12	8.1	100	0.09 \pm 0.09, (0.04 - 0.29)
Mammals				
Polar bear (<i>Ursus maritimus</i>) -plasma	20	n.d.	95	0.14* \pm 0.16*, (<0.018 - 0.66)
Ringed seal (<i>Phoca hispida</i>) -plasma	10	n.d.	10	0.026* \pm 0.03*, (<0.01 - 0.04)

*For the samples where TBPH was <Method Detection Limit, 1/2 MDL was used as a value for calculating the arithmetic mean.

Vorkamp *et al.* (2015), analysed biota samples collected in Central East Greenland in 2012 and included black guillemot (*Cepphus grylle*) eggs (n = 3), glaucous gull (*Larus hyperboreus*) liver (n = 4), blubber of ringed seal (*Pusa hispida*) (n = 5) with additional ringed seal samples from West Greenland (n = 4), and polar bear (*Ursus maritimus*) adipose tissue (n = 5). The overall

detection frequency was 24%. TBPH was not detected in glaucous gull or ringed seal. It was however detected in all three samples of black guillemot eggs and in three of five samples of bear adipose tissue with a mean and (range) concentrations of 0.061 (0.050-0.066) µg TBPH/kg ww and 0.26 (<0.128 – 0.402) µg TBPH/kg ww, respectively (see **Table 9**).

Table 9. Concentrations of TBPH in species from the Danish Arctics 2012 - (Central East and West Greenland) (Vorkamp *et al.*, 2015)

Species	n	Lipid (%)	Detection frequency (%)	Concentration (µg TBPH/kg ww) Arithm. mean (range)
Birds				
Black guillemot (<i>Cepphus grille</i>) -egg	3	10.2	100	0.061, (0.020 – 0.066) – Central East Greenland
Glaucous gull (<i>Larus hyperboreus</i>) -liver	4	5.3	0	<0.025* – Central East Greenland
Mammals				
Polar bear (<i>Ursus maritimus</i>) -adipose tissue	5	86.4	60	0.26, (<0.128 – 0.402) – Central East Greenland
Ringed seal (<i>Phoca hispida</i>) -blubber	5	93.1	0	<0.14* – Central East Greenland
	4	94.2	0	<0.13* – West Greenland

*Method detection limit

3.3.3 Summary and discussion of long-range transport

The AOPWIN predicted environmental half-life for TBPH of 5.9 hours based on reactions with hydroxyl radicals in the gas-phase which is most probably an underestimation of the half-life in air. As ≥99.8% of TBPH is predicted to be sorbed to airborne particulates and the sorbed fraction to particulates likely increases the residence time in air and the potential for TBPH for long-range transport, which is confirmed by air monitoring data.

TBPH has been detected in air in locations remote from known point sources, such as the Arctic and the Tibetan Plateau, indicating potential for long-range atmospheric transport. It has also been detected in other media in the Arctic, such as water and biota (e.g., ringed seal and polar bear).

In summary, TBPH is capable of reaching regions far away from the point of initial emission, as demonstrated in findings from the Tibetan Plateau and the Arctic, which indicates long-range transport potential.

3.4 Bioaccumulation

3.4.1 Bioaccumulation in aquatic organisms (pelagic & sediment organisms)

There are four available experimental studies, three laboratory studies (Barr *et al.*, 2010; Nacci *et al.*, 2018; Unpublished, 2018) and one field/mesocosm study (de Jourdan *et al.*, 2013). 3.4.1.1 Screening information

According to REACH Chapter R.11 (ECHA, 2017a), substances having a log K_{ow} greater than 4.5 screen as potentially (very) bioaccumulative for aquatic organisms.

For TBPH a log K_{ow} value of 10.2 has been determined experimentally following an OECD TG 117, HPLC method. As this log K_{ow} value is > 4.5, it is concluded that TBPH screens as potentially (very) bioaccumulative for aquatic organisms.

3.4.1.2 Laboratory studies

As a consequence of an ECHA compliance check decision, the bioaccumulation potential of TBPH was investigated in a study according to OECD Guideline 305 (Unpublished, 2018). This study is considered to be reliable with restrictions. Juvenile rainbow trout (*Oncorhynchus mykiss*) with a weight of 2.06 ± 0.20 g and length 5.57 ± 0.15 cm at the start of the study, were used in the experiment. In total 57 fish were exposed to TBPH via the feed under flow-through conditions for a period of 28 days. The measured concentration in the feed was 652 mg TBPH/kg feed (nominal 1000 mg TBPH/kg feed). The exposure period was followed by a depuration phase of 28 days when the fish were fed uncontaminated feed. An equally sized control group with fish of the same age fed with uncontaminated food was run in parallel.

The TBPH exposed group and the control group were both fed at a fixed ratio of 2 % of body weight per day. Fish were held in 100 L aquaria (75 L water) with a maximum fish-to-water loading rate of 0.1 to 1.0 g fish (wet weight) per litre of water per day. The flow rate was at least 15.6 L/h, the temperature $15 \pm 2^\circ\text{C}$ and the oxygen was > 60% throughout the test.

Six fish per control and treatment, were sampled twice during the uptake phase (days 14 and 28) and five times during depuration (days 31.5, 35, 42, 49 and 56). Samplings were performed before the daily feeding to obtain samples from fasted fish. Weight and length were recorded before the fish were sacrificed for analytical analysis. In addition, three fish of each population were sampled for monitoring of lipid contents at the end of uptake and depuration phase.

TBPH concentrations in fish during the uptake phase ranged from 2820 μg TBPH/kg ww to 5876 μg TBPH/kg ww on day 14 (mean 3979 ± 1265 μg TBPH/kg ww), and from 4837 μg TBPH/kg ww to 11020 μg TBPH/kg ww on day 28 (mean 8583 ± 2521 μg TBPH/kg ww). Whether or not steady state was reached during the uptake phase could not be determined. During depuration, the TBPH concentrations in fish decreased slowly from a mean of 1848 ± 172 μg TBPH/kg ww at the first sampling day 31.5 to 654 ± 160 μg TBPH/kg ww day 56.

Fish grew during the study and the average fish weight at the start of the test was 2.06 ± 0.2 g ($n = 50$), and after 56 days 12.1 ± 1.09 g in the control group ($n = 6$) and 10.15 ± 2.27 g in the TBPH treated group. There was no statistically significant difference between treatment group and control and no difference in growth rate between uptake and depuration phase. The fish lipid content in the TBPH treated group was 5.5 ± 0.73 % ($n = 3$) at the end of the uptake period (day 28) and 7.8 ± 0.54 % ($n = 3$) at the end of the depuration period (day 56).

The substance was poorly absorbed and the assimilation efficiency was calculated to 0.011. The growth and lipid corrected BMF was 0.038. The depuration was slow with a growth corrected depuration rate constant of 0.015 and a growth corrected half-life of 46.2 days (see **Table 10**)

Table 10: BMF, depuration rate constants and half-life (Unpublished, 2018).

Treatment	Kinetic BMF	Depuration rate constant (d ⁻¹)	Half-life (d)
Uncorrected	0.0048	0.044	15.6
Growth corrected*	0.0143	0.015	46.24
Growth and lipid corrected	0.0381	-	-

* Growth rate constant 0.0294

Fish BCFs for TBPH were calculated using the 15 models within the OECD TG 305 BCF estimation tool using the information given in the study report. The results are presented in **Figure 1**.

Inputs		Outputs			
Variable	Value	Method 1			
Mean weight at test start (g)	2	inputs for K1	K1	BCF Est.	Ref.
Uptake phase duration (days)	28	weight	433,09	24076,7	Hayton and Barron (1990)
Growth rate, K _g (day ⁻¹)	0,02937	weight	595,86	33125,5	Erickson and McKim (1990a)
Log K _{ow}	10,2	weight	591,55	32885,6	Barber et al. (1991)
K _{2g} (K ₂ - K _g)	0,01499	weight	382,32	21254,1	Barber (2003) - observed
Mean fish lipid uptake end or depuration start (fraction)	0,045	weight	612,12	34029,2	Barber (2001)
Mean fish lipid depuration end (fraction)	0,075	weight	115,91	6443,9	Streit and Sire (1993)
Depuration phase duration (days)	28	weight	477,85	26564,8	Erickson and McKim (1990b)
BMF _{gl}	0,0381	weight	406,35	22590,1	Sijm et al. (1995)
		weight	490,57	27272,1	Barber (2003) - calibrated
		log Kow	2731,49	151850,8	Tolls and Sijm (1995)
		log Kow	3015,78	167655,2	Spacie and Hamelink (1982)
		weight, log Kow	105,74	5878,3	Hendriks et al. (2001)
		weight, log Kow	Kow too high, set 1	Inputs incomplete	Thomann (1989)
		Method 2			
		input	Estimated K1	BCF Est.	Ref.
		K _{2g}	603,80	33566,9	Brookes and Crooke (2012)
		Method 3			
		input	Estimated K1	BCF Est.	Ref.
		BMF _{gl}	15,85	881,1	Inoue et al (2012)

Figure 1. Output from OECD TG 305 BCF estimation tool based on data from Unpublished (2018).

The results indicate a BCF >5000 for all method 1 models (except 1) and for method 2 but not for method 3.

A benchmark approach is used in order to compare the laboratory depuration rate constants and BMF values for TBPH (Unpublished, 2018) with the laboratory depuration rate constants and BMF values for substances identified as SVHC based on their vPvB properties. The depuration rate constants and BMF values for rainbow trout reported in **Table 11** indicates that TBPH has a depuration rate constant in the lower range and a BMF within the range of values for the SVHC substances having vB properties.

Table 11: Comparison of laboratory Depuration rate constants and BMF values in Rainbow Trout (*Oncorhynchus mykiss*) for TBPH and SVHC substances identified as vB

Substance	Log Kow	Assimilation efficiency (%)	Half-life growth corrected (days)	Depuration rate constant (K_2) (day^{-1})	BMF	Reference
TBPH	10.2	1	46	$K_{2g} = 0.015$	$\text{BMF}_{\text{KgL}} = 0.038$	Unpublished 2018
o-Terphenyl vPvB constituent of Terphenyl, hydrogenated (EC Number: 262-967-7)	5.52	20	8.1	$K_2 = 0.085$	$\text{BMF}_{\text{KgL}} = 0.59$ $\text{BMF}_{\text{KgL}} = 0.2$	ECHA (2018)
Dechlorane Plus	≥ 9	$\sim 0.8-2$ (anti-DP) $\sim 1.6-7.5$ (syn-DP)	$30-40$ (anti-DP) $50-70$ (syn-DP)	$K_{2g} = 0.010 - 0.013$ (syn isomer) And $K_{2g} = 0.017 - 0.023$ (antiisomer) (lipid normalised)	0.023 (anti-isomer) $\text{BMF}_{\text{KgL}} = 0.046 - 0.062$ (syn-isomer)	ECHA (2017b)
Benz[a]anthracene	6		< 2	$K_{2g} = 1.572$	$\text{BMF} = 0.001$	Brookes & Crookes (2012), ECHA (2017c)
Methoxychlor*	5.1 - 5.7			$K_{2g} = 0.124$	0.16	Brookes & Crookes (2012), ECHA (2020)

*Not identified as SVHC under REACH, however nominated to the Stockholm Convention by the EU Commission

Nacci *et al.* (2018) investigated the uptake and depuration of TBPH in the estuarine fish, Atlantic killifish (*Fundulus heteroclitus*) after dietary exposure. Diets were amended with TBPH (TBPH_LO diet, 139 mg TBPH/kg dry wt, or TBPH_HI diet, 4360 mg TBPH/kg dry wt). The polychlorinated biphenyl congener 2,2',4,4',5,5' hexachlorobiphenyl (PCB153 diet, 13 mg/kg dry wt), was included as a positive control for bioaccumulation.

The design was similar to OECD guideline 305 dietary bioaccumulation. This study is considered to be reliable with restrictions. During the experimental period (42 days), fish were fed acetone amended control or contaminated diets from 0 to 28 d (uptake period), followed by a depuration period of 14 days during which time fish were fed control diet.

Wild-caught killifish (2 – 3 g wet wt) were kept in 38-L tanks receiving flowing seawater at a rate of 1.3 L/min. Each treatment consisted of 40 fish distributed in 10 replicate tanks, except for the PCB treatment, for which 6 tanks were used (no depuration period). Each tank contained 4 fish (2 males and 2 females). The fish were fed twice daily, and the daily feeding rate based on an average initial fish weight of 2.35 g wet wt (= 0.58 g dry wt) was approximately 15.7%

based on dry weight. This gave a daily exposure of 51 µg TBPH/tank/day in the TBPH_LO diet, 1593 µg TBPH/tank/day in the TBPH_HI diet and 5 µg PCB 153/tank/day in the PCB 153 diet.

Eight fish from each treatment were sampled on day 14. On day 28 (end of uptake period) 16 fish from each treatment were sampled. Eight fish per treatment were sampled during the depuration period on days 35 and 42 of the study. Bioaccumulation of TBPH accounted for 0.46 % of the total amount of chemical provided over 28 days of feeding at the lower exposure level (averaging male and female fish values; **Table 12**). The BMF defined as the ratio of tissue to dietary concentrations was ca 0.02. At the higher exposure level, a much lower fraction of TBPH was taken up by the fish; only 0.1 % of the total amount of TBPH provided via feeding was accounted for in fish and the BMF was 0.005 (mean male + female). This concentration dependence indicates reduced bioavailability with increasing exposure. Thus, the low BMFs derived in this study may not represent a worst case scenario as in a field situation, exposure concentrations are expected to be much lower (thus a higher BMF is expected). The values for PCB 153 are given in **Table 12** for comparison.

The depuration rate constant (k_2) was 0.031 day^{-1} and the time to depurate to 50 % of the 28-day TBPH concentration ($T_{1/2}$) was approximately 22 days. This half-life is not growth corrected.

It is not possible to calculate BCF from these BMF-values, as described in OECD TG 305, since only some of the necessary input data are possible to deduce from the publication but not all (e.g., the mean fish lipid at the end of the uptake period and at the end of the depuration period).

Table 12: BMF and substance concentrations in diet and fish (Nacci et al., 2018).

Treatment	Conc. in diet (µg/kg dw)	Sex	Conc in fish at day 28 (µg/kg dw)	BMF	Substance accounted for in fish (%)	Conc in fish (µg/kg lipid)
PCB 153 control	13	F	24			
		M	34			
PCB 153	12 993	F	13 115	1.01	22.93	66 677
		M	14 883	1.15	26.02	102 372
TBPH control	25	F	ND			
		M	ND			
TBPH Low	139 000	F	2319	0.017	0.38	7748
		M	3314	0.024	0.54	14 089
TBPH High	4 360 000	F	24 738	0.006	0.13	90 145
		M	16 174	0.004	0.08	72 245

Bearr et al., (2010) exposed fathead minnow (*Pimephales promelas*) to Firemaster® 550, Firemaster® BZ-54 or DEHP via the food for 56 d with a subsequent depuration period of 22 days when all fish were fed control food. Firemaster® 550 is a mixture of triaryl phosphate isomers, triphenyl phosphate, and Firemaster® BZ-54. Firemaster® BZ-54 is a mixture of TBPH and 2-ethylhexyl 2,3,4,5-tetrabromobenzoate (TBB). The purpose of the study was to investigate if TBB and TBPH are bioavailable and if they adversely affect DNA integrity in fish. For the latter purpose, liver and blood cells were collected and assessed for DNA damage.

The test substances were dissolved in cod liver oil and mixed into fish food. Control food included cod liver oil. Test substance concentration in the fish food is shown in **Table 13**.

Table 13: Concentrations of TBPH and TBB in amended diets mean of three replicates ± standard error (Bearr *et al.*, 2010).

Treatment	% Lipid	Total (mg/kg feed - wet weight)	
		TBPH	TBB
Control	6.5 ± 0.3	<0.26 ± 0.014	0.20 ± 0.053
Firemaster® 550	7.4 ± 0.7	744.7 ± 85.97	1658 ± 198.9
Firemaster® BZ-54	7.7 ± 1.0	907 ± 166.3	2087 ± 385.0

Twenty fish held in 40 L aquaria (5 fish/aquarium) were used for each treatment and 15 for control. The fish were fed 0.2 g food/days (6% of fish body weight). The expected daily intake per fish was 150 µg TBPH and 330 µg TBB in the FM 550 feed, and 180 µg TBPH and 420 µg TBB in the BZ-54 feed. Every other day 50% of the water was exchanged 6 h after feeding. Analysis of TBPH and TBB and appearance of any metabolites was performed day 0 and day 56 on carcasses were gonads, liver and brain first had been removed.

The average length and weight of the fish at test initiation was 61 ± 1 mm and 2.42 ± 0.21 g, respectively. After 78 days, the fish length was 67 ± 1 mm and the weight was 3.19 ± 0.21 g.

Both TBPH and TBB concentrations in fish on day 56 were significantly higher than day 0. The highest amount of chemical measured in a single BZ-54-fed fish was 1075 ng of TBPH and 800 ng of TBB. These numbers represent 0.59 and 0.19% of the daily dosage for TBPH and TBB in the BZ-54- feed, respectively. Total recoverable TBB and TBPH were 70% less in FM 550-fed fish. However, these fish were probably not in a good condition as the survival in this treatment group was only 63% as compared to 83 and 88% in the control and BZ-54 treatments, respectively. Unfortunately, the information given in the publication did not allow estimation of the BMF or the depuration half-life.

During analysis of the fish tissue samples, several peaks were observed in the GC/MS chromatograms in addition to the parent compounds. The mass spectrum of these peaks suggested they were brominated metabolites of TBB. In a preliminary study, BZ-54 was incubated with active or heat killed common carp (*Cyprinus carpio*) liver microsomes for 2 h at 25°C (n = 3). The concentration of TBB was 73.1 ± 1.3 % less in the active microsome samples than in the heat-killed sample while no difference (0.0 ± 4.3 %) was detected with respect to the concentration of TBPH. This suggests that TBB is rapidly metabolised in common carp microsomes, but TBPH is not.

3.4.1.3 Field/mesocosm studies

De Jourdan *et al.* (2014) investigated the environmental fate of three brominated flame retardants, including TBPH, in aquatic mesocosms. Mesocosms with a depth of 1.2 m and a diameter of 3.9 m were filled with water to approximately 1 m (ca 12000 L). Sediment trays 52.1 x 25.4 x 5.7 cm containing organic rich soil (OC 10% dw) were added to each mesocosm so that > 50% of bottom surface was covered. Three mesocosms were treated (2 July 2008) in triplicate with BZ-54 (a 20:80 commercial mixture of TBPH and TBB), in addition three mesocosm were used as solvent controls. The test substance was applied by subsurface injection of BZ-54 dissolved into 125 mL of dimethyl sulfoxide and 5 mL of toluene aiming for a concentration of 500 µg compound/kg sediment in the upper 5 cm of sediment. In the solvent control an equal volume of the solvent mixture was administered to control mesocosms, representing 0.001% solvent v/v. Fathead minnow (*Pimephales promelas*) were allowed to acclimate for 10 d prior to treatment in their randomly assigned mesocosm. Minnows were contained in mesh enclosures (22 cm diameter, 40 cm long) with 12 minnows (undetermined sex, ~5 cm in length) per

enclosure and 2 enclosures per mesocosm. The minnows were not fed but foraged on the zooplankton community. A plastic (10 cm x 10 cm x 5 cm) container was placed at the bottom of each enclosure and filled with the same sediment as on the bottom of the mesocosms. Samples of the water-column (~4 L) for analyses of water quality parameters (e.g., O₂, pH) were taken at -4 days, 1 hour, 4 hours, 1 day, 2 days, 4 days, 7 days, 14 days, 21 days, 28 days, 35 days, 42 days, 49 days, 56 days, and 70 days (10 September 2008) after treatment. After 42 days, fish were transferred to new mesh cages in 1 of the 3 control mesocosms for the depuration phase. Fish were sampled during the exposure period at 7 days, 14 days, 28 days, and 42 days and during the depuration period at 49 days and 70 days. On each sampling day, 3 minnows per mesocosm were randomly sampled. TBPH was only measurable in 1 fish from 1 mesocosm day 7, in 2 fish (1 from each of two mesocosms) day 14 and in 1 fish from 1 mesocosm day 28. However, the exposure in this study is unknown. Due to the limited water solubility, it is assumed that the concentration in water was very low and that the fish were exposed to TBPH via the food only. The TBPH concentration in the zooplankton that the fish fed on was however not measured. This study does therefore not allow to make conclusions on the bioaccumulation of TBPH in fish.

3.4.2 Bioaccumulation in terrestrial organisms (soil dwelling organisms, vertebrates)

With a measured log K_{ow} of 10.2 and an estimated log K_{oa} of 15.4 (KOAWIN v1.10) TBPH fulfils the screening criteria for terrestrial bioaccumulation (log K_{ow} >2 and log K_{oa} >5). No experimental studies on bioaccumulation in terrestrial species are available. The available toxicokinetic data (see section 4.1.1.1) indicate that TBPH is poorly absorbed and poorly metabolised and is mainly excreted unchanged via faeces. This is what can be expected for a substance with a log K_{ow} >10. However, a small fraction of the substance seems to be accumulating in tissues of the exposed organisms. Studies of repeated oral exposures showed that while only a small amount of TBPH is absorbed, it has the potential to accumulate in adrenal and liver tissue, largely as the parent substance (see section 4.1.1.1.) This is apparent from the available monitoring data that suggests that TBPH accumulates in air breathing animals. TBPH has been detected in liver and eggs from several bird species including raptors preying on terrestrial species as well as birds that feed on aquatic organisms also in the Arctic. It is not possible to derive BMF values for the different bird species from these monitoring studies as the concentrations in their feed is not known.

Furthermore, TBPH has been detected in blubber from marine mammals such as finless porpoise and dolphins and in the liver of the arctic species ringed seal and in the plasma of polar bears. To conclude, TBPH is present in a wide range of air breathing birds and mammals including top predators both in more industrialised areas as well as in remote regions, such as the Arctic.

3.4.3 Field data

The studies by Jin *et al.* (2016), Zheng *et al.* (2018) and Hou *et al.* (2022) investigated the relationship between trophic level and concentration of TBPH in terrestrial and aquatic food webs, respectively. Jin *et al.* (2016) found a significant positive relationship between the concentrations of TBPH and δ¹⁵N in residential and predatory bird species in a terrestrial food web in South Korea. Zhen *et al.* (2018) identified a positive relationship between trophic levels and the lipid-normalised concentration of TBPH in a limnic food web in Lake Taihu in China. Also, Hou *et al.* (2022) found a positive correlation between the lipid normalised concentrations of TBPH and trophic level in a marine food web in the South Chinese Sea. This correlation was however not statistically significant.

Jin *et al.* (2016), analysed brominated diphenyl ethers and NBRs including TBPH in the livers of predatory and non-predatory birds in Korea and in addition investigated if there was a correlation between TBPH concentrations and trophic level (measured as δ¹⁵N). Ten bird species (total

individuals, n = 69) were obtained from the National Science Museum in Daejeon, Korea during the period of 2010-2011. All birds were found dead from several causes, e.g., roadkill, poisoning, or starvation. Most bird samples were from the same area, Paju, Gyeonggi-do (n = 57). Of the ten species Eurasian eagle owl (*Bubo bubo*), common kestrel (*Falco tinnunculus*), collared scops owl (*Otus lempiji*), and blacktailed gull (*Larus crassirostris*) are regarded as residential predatory birds; the common buzzard (*Buteo buteo*), northern goshawk (*Accipiter gentilis*), cinereous vulture (*Aegypius monachus*), and brown hawk owl (*Ninox scutulata*) are regarded as migrant predatory birds. Oriental turtle dove (*Streptopelia orientalis*) and spotbilled duck (*Anas poecilorhyncha*) are regarded as residential herbivore and insectivore birds, respectively.

Analyses were performed using GC/MS. Identification and quantification were conducted with electron capture negative ionisation and selected ion monitoring (m/z 79 and 81). TBPH had the highest occurrence of the analysed NFBs. The detection rate was 54%. The overall mean concentration of TBPH was 21.3 µg/kg lipid weight. The highest concentrations were found in Eurasian eagle owl and Common kestrel while the lowest concentrations were found in the non-predatory birds, spot-billed duck and oriental turtle dove see **Table 14**.

The TBPH concentration was not significantly correlated with $\delta^{15}\text{N}$ values when all samples were plotted together. However, three residential and carnivorous predatory species, Eurasian eagle owl (*B. bubo*), common kestrel (*F. tinnunculus*), and collared scops owl (*O. lempiji*) which were all sampled in the same area (Paju, Gyeonggi-do), showed a significant positive relationship between the concentrations of TBPH and $\delta^{15}\text{N}$ ($r^2 = 0.63$, $p = 0.018$). This study is considered reliable with restriction.

Table 14: TBPH concentration in birds (liver) from Korea (Jin *et al.*, 2016)

Species	Sampling location	n	Feeding habits	Migratory behaviour	TBPH in liver µg/kg lipid weight Mean (Range)	δ15N (‰) Mean ± standard deviation
Eurasian eagle owl (<i>Bubo bubo</i>)	Paju, Gyeonggi-do	5	Carnivore (pheasants, rabbits, rodents)	Resident	170 (2.24-803)	8.8 ± 1.5
Common kestrel (<i>Falco tinnunculus</i>)	Paju, Gyeonggi-do	4	Carnivore (small birds, reptiles, and insects)	Resident	52.1 (2.88-110)	7.7 ± 1.0
Collared scops owl (<i>Otus lempiji</i>)	Paju, Gyeonggi-do	6	Carnivore (insects, small birds, rodents, and crustaceans)	Resident	10.8 (<0.75-27.8)	6.5 ± 1.3
Black-tailed gull (<i>Larus crassirostris</i>)	Yeonggwang, Jeollanam-do; Ulleungdo and Dokdo islands	8	Piscivore (fish and amphibians)	Resident	2.57 (<0.75-9.10)	12.9 ± 0.1
Brown hawk owl (<i>Ninox scutulata</i>)	Paju, Gyeonggi-do Gunsan, Jeollabukdo	9	Carnivore (insects, birds, rodents, and bats)	Migratory (Philippines and Indonesia in summer)	20.8 (<0.75-80.4)	5.5 ± 0.8
Northern goshawk (<i>Accipiter gentilis</i>)	Paju, Gyeonggi-do	6	Carnivore (small birds and small mammals)	Migratory (Russia, China in winter)	6.5 (<0.75-22.4)	7.9 ± 1.5
Cinereous vulture (<i>Aegypius monachus</i>)	Paju, Gyeonggi-do	7	Carnivore (mainly carrion)	Migratory (Mongolia in winter)	1.86 (<0.75-8.52)	9.5 ± 1.2
Common buzzard (<i>Buteo buteo</i>)	Paju, Gyeonggi-do	7	Carnivore (small birds and rodents)	Migratory (Russia in winter)	12.2 (<0.75-63.7)	7.0 ± 0.58
Spot-billed duck (<i>Anas poecilorhyncha</i>)	Paju, Gyeonggi-do	6	Insectivore and herbivore (insects and seeds)	Resident	1.98 (<0.75-3.77)	10.0 ± 0.7
Oriental turtle dove (<i>Streptopelia orientalis</i>)	Gyeonggi-do; Gyeongsangbuk-do; Jeollabok-do	11	Herbivore (nuts and seeds)	Resident	<0.75	5.9 ± 1.7

Zheng *et al.* (2018) measured the concentrations of 8 (NBFRs), including TBPH, in 17 species from Lake Taihu, South China. The food web included primary producers (bioeston/plankton), four invertebrates species including freshwater mussel (*Anodonta*), clam (*Lamellibranchia*), crayfish (*Procambarus clarkii*), and snail (*Bellamya purificata*), 12 fish species including rice field eel (*Monopterus albus*), blunt-snout bream (*Megalobrama amblycephala*), whitebait (*Hemisalanx prognathous*), crucian (*Carassius auratus*), carp (*Carassius cuvieri*), pipefish (*Tylosurus crocodilus*), silver fish (*Protosalanx hyalocranius*), whitefish (*Alburnus*), catfish (*Silurus asotus*), redfin culter (*Cultrichthys erythropterus*), wolffish (*Anarrhichtys Ocellaus*), and yellow-head catfish (*Pelteobagrus fulvidraco*). Sampling was performed in August 2014 and May 2015. Whole bodies of seston/plankton, soft tissues of invertebrates and muscles were stored at - 20 °C prior to analysis. Separation was achieved on an HP-5 capillary column and the

analysis of TBPH was performed using GC-ECNI-MS through selected ion monitoring (SIM) for m/z ^{79}Br and ^{81}Br .

The trophic level (TL) of the species was determined by stable isotope analysis. In addition, liver microsomes of crucian (trophic level [TL]: 2.93), catfish (TL: 3.86), and yellow-head catfish (TL: 4.3) were used to measure the metabolic rates of the different NFBs. TBPH showed no significant metabolism after 24 h of incubation with the liver microsomes of the three species.

The average concentrations of TBPH in all of the sampled species was $0.87 \pm 0.91 \mu\text{g TBPH/kg ww}$, and the highest concentrations ($3.32 \pm 5.73 \mu\text{g TBPH/kg ww}$) was detected in whitefish (**Table 15**).

Table 15: Concentrations of TBPH in biota sampled in August 2014 and May 2015 in Lake Taihu, South China (Zheng *et al.*, 2018)

Species	Trophic Level Mean \pm SD	n	TBPH ($\mu\text{g/kg ww}$) mean \pm SD (range)	Concentrations refers to
Plankton/seston	2.00 \pm 0.27	6	0.143 \pm 0.090 (<MDL-0.27)	Whole body
Freshwater mussel	1.08 \pm 0.53	6	0.051 \pm 0.0438 (<MDL-0.0431)	Soft tissue
Clam	1.71 \pm 0.17	6	0.0762 \pm 0.0989 (<MDL-0.251)	Soft tissue
Crayfish	1.59 \pm 0.53	6	<MDL	Soft tissue
Snail	3.16 \pm 0.15	6	0.507 \pm 0.445 (<MDL-1.280)	Soft tissue
Ricefield eel	2.82 \pm 0.23	6	1.100 \pm 0.766 (<MDL-2.540)	Muscle
Blunt-snout bream	3.30 \pm 0.04	2	2.130 \pm 0.101 (2.050–2.200)	Muscle
Whitebait	2.29 \pm 0.05	5	1.370 \pm 1.850 (0.188–4.610)	Muscle
Crucian	2.93 \pm 0.10	6	0.211 \pm 0.135 (0.0987–0.394)	Muscle
Carp	3.42 \pm 0.25	3	0.245 \pm 0.192 (<MDL-0.437)	Muscle
Pipefish	3.48 \pm 0.18	3	0.664 \pm 0.311 (0.384–0.998)	Muscle
Silver fish	3.31 \pm 0.07	6	0.0776 \pm 0.0067 (<MDL-0.0774)	Muscle
Whitefish	3.85 \pm 0.65	6	3.320 \pm 5.730 (<MDL-14.900)	Muscle
Catfish	3.86 \pm 0.12	5	0.713 \pm 0.480 (0.386–1.538)	Muscle
Redfin culter	3.90 \pm 0.03	7	1.830 \pm 1.450 (<MDL-4.540)	Muscle
Wolfish	3.99 \pm 0.11	3	1.040 \pm 0.186 (0.897–1.250)	Muscle
Yellow-head catfish	4.30 \pm 0.06	6	1.230 \pm 0.400 (0.844–1.910)	Muscle

A significantly positive relationship was found between trophic levels and the lipid-normalised concentration of TBPH ($p = 0.004$) (see **Figure 2**). The trophic magnification factor (TMF) was 2.42. This study is considered reliable with restriction.

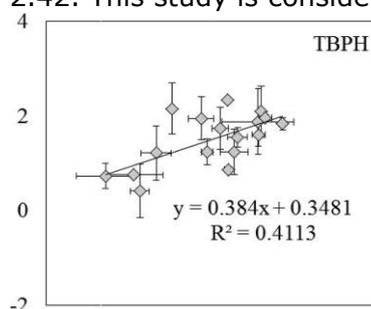


Figure 2. Relationship between trophic level and concentration of TBPH in biota from Lake Taihu, South China (Zheng *et al.*, 2018)

Hou *et al.* (2022) studied the concentrations and composition profile of novel brominated flame retardants (NBFR), including TBPH, in tropical biota, trophic transfer potential and trophodynamics in the tropical marine food web and biotransformation in marine fish liver. The samples were collected from the coral reef waters of Xisha Islands, South Chinese Sea, in October – November 2020 using Agassiz trawl and macroplankton trawl. All biota were cleaned

with Milli-Q water and length and weights were recorded. Whole bodies of invertebrates and fish muscle were dissected and transferred to the laboratory on dry ice and stored at -80°C until analysis. All biota were homogenised after being freeze-dried for at least 72 hours. Samples of surface seawater (n=8) and sediment (n=8) were also collected in the area and stored at -20°C until analysis. It is based on the information provided in Table S2 in the supporting information concluded that the concentrations in invertebrates are based on soft tissues (i.e. not whole bodies including shells, etc.). TBPH was analysed using a GC-MS in an electron-capture negative chemical ionisation mode (ion 1: m/z 79 and 81, ion 2: 462) with a DB-5MS capillary column to separate the NBFR. The freeze-dried biota was also analysed to determine the stable isotopic ratios of carbon ($\delta^{13}\text{C}$) and nitrogen ($\delta^{15}\text{N}$). In order to ensure analysis stability, one standard solution was run with each batch of 10 samples. The measured concentrations of NBFR in procedural blanks were all below the method detection limit (MDL). During all statistical analysis, values below the MDL were set to ½ MDL. The TBPH MDL was 0.012 µg TBPH/kg lipid weight. The recovery of TBPH in organism samples was $83.7 \pm 2.36\%$. The accuracies for the stable $\delta^{13}\text{C}$ and $\delta^{15}\text{N}$ isotope analysis were 0.02 and 0.05%, respectively. The authors estimated trophic level (TL) based on the assumption that zooplankton occupy TL 2.0 and a $\delta^{15}\text{N}$ of 3.8, using the equation:

$$\text{TL} = 2 + [(\delta^{15}\text{N}_{\text{sample}} - \delta^{15}\text{N}_{\text{plankton}})/3.8]$$

The trophic magnification factor (TMF) was calculated using the slope coefficient from the correlation between the lipid normalised concentration and TLs of individual organisms:

$$\text{TMF} = 10^b, \text{ where } b \text{ is the slope in the equation } \text{Log } C_{\text{biota}} = a + b \times \text{TL}$$

The relative carbon source was calculated to identify the relative contribution of benthic vs. pelagic carbon sources, using mathematically adjusted $\delta^{13}\text{C}$ values and the carbon/nitrogen ratios. The stable isotope analysis confirmed that the sampled biota species represents a wide range of trophic positions in this tropical marine food web where the marine shells mainly are herbivorous, crabs and sea cucumbers mainly are omnivorous, the herbivorous fish species, rabbit- and parrotfishes, are low-order predators and the carnivorous fish species are higher order predators. Calculated relative carbon sources were distributed near its mean value and within its boundaries for the same food web for almost all of the studied species. Fresh liver tissues from two fish species, the grouper *Epinephelus fasciatus* (TL 3.96 ± 0.06) and sweetlips *Plectorhynchus orientalis* (TL 3.84 ± 0.05), were used to study potential differences in hepatic metabolism rates at different trophic levels. The recovery of TBPH in the microsome samples was $89.7 \pm 4.64\%$.

The detection frequency of TBPH in seawater, sediments and biota samples was 12.5%, 62.5% and 78.4%, respectively. The measured concentrations of TBPH in seawater, sediments and biota is presented in **Table 16**.

Table 16: Concentration of TBPH in seawater, sediment and biota sampled from a tropical marine food web from the coral reef waters of Xisha Islands, South Chinese Sea in October – November 2020 (Hou et al., 2022)

	n	Habitat	Feeding	Trophic Level Mean ± standard deviation	Concentration (µg TBPH/kg lipid weight, unless otherwise specified) Mean ± standard deviation	Concentrations refers to
Seawater	8	-	-	-	0.037 pg TBPH/L	
Sediment	8	-	-	-	0.181± 0.073 µg/kg dw	

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Sea shells						Soft tissue
<i>Trochus sacellum</i>	5	Benthic	Herbivorous	2.46±0.07	0.126±0.044	
<i>Turbo chrysostomus</i>	6	Benthic	Herbivorous	2.33±0.10	0.155±0.059	
<i>Strombus</i>	3	Benthic	Omnivorous	2.22±0.09	0.109±0.009	
<i>lentiginosus</i>	5	Benthic	Herbivorous	2.90±0.20	0.266±0.042	
<i>Haliotis</i>	3	Benthic	Herbivorous	2.37±0.12	0.163±0.030	
<i>diversicolor</i>						
<i>Nerita striata</i>						
Sea cucumber						Soft tissue
<i>Bohadschia</i>	4	Benthic	Herbivorous	2.80±0.38	0.020±0.009	
<i>marmorata</i>	3	Benthic	Omnivorous	2.50±0.31	0.021±0.002	
<i>Holothuria hilla</i>	3	Benthic	Omnivorous	2.18±0.31	0.023±0.002	
<i>Thelenota ananas</i>						
Crab						Soft tissue
<i>Etisus dentatus</i>	5	Benthic	Omnivorous	2.92±0.12	0.010±0.008	
<i>Calcinus laevimanus</i>	6	Benthic	Omnivorous	2.59±0.13	<MDL*	
<i>Clibanarius</i>	4	Benthic	Omnivorous	2.00±0.14	0.036±0.039	
<i>corallinus</i>						
Fish – goatfish						Muscle
<i>Upeneus sulphureus</i>	6	Benthic	Carnivorous	3.64±0.08	0.090±0.014	
<i>Parupeneus</i>	6	Benthic	Carnivorous	3.83±0.03	0.065±0.008	
<i>trifasciatus</i>	3	Benthic	Carnivorous	3.53±0.06	0.069±0.014	
<i>Parupeneus</i>						
<i>barberinus</i>						
Fish – grouper						Muscle
<i>Epinephelus</i>	3	Benthic	Carnivorous	3.96±0.06	0.118±0.043	
<i>fasciatus</i>	4	Benthic	Carnivorous	3.86±0.10	0.128±0.068	
<i>Variola louti</i>	3	Benthic	Carnivorous	4.04±0.13	0.369±0.066	
<i>Cephalopholis argus</i>	3	Benthic	Carnivorous	3.50±0.04	0.083±0.036	
<i>Epinephelus merra</i>						
Fish – rabbitfish						Muscle
<i>Siganus puellus</i>	3	Benthic	Herbivorous	3.21±0.03	0.127±0.037	
<i>Siganus argenteus</i>	3	Benthic	Herbivorous	3.35±0.07	0.153±0.055	
<i>Siganus</i>	3	Benthic	Herbivorous	3.25±0.13	0.060±0.005	
<i>punctatissimus</i>						
Fish parrotfish						Muscle
<i>Scarus tricolor</i>	3	Benthic	Herbivorous	3.03±0.09	0.190±0.053	
<i>Scarus schlegeli</i>	3	Benthic	Herbivorous	3.02±0.10	0.059	
<i>Scarus sordidus</i>	4	Benthic	Herbivorous	3.03±5.18	0.159±0.032	
Fish – wrasse						Muscle
<i>Cheilinus trilobatus</i>	3	Pelagic	Carnivorous	3.30±0.40	0.081±0.040	
<i>Hemigymnus</i>	3	Benthic	Carnivorous	3.68±0.02	0.235±0.109	
<i>melapterus</i>						
Fish – sweetlips						Muscle
<i>Plectorhynchus</i>	3	Benthic	Carnivorous	3.84±0.05	0.080±0.009	
<i>orientalis</i>						
Fish – filefish						Muscle
<i>Cantherhines</i>	3	Benthic	Carnivorous	3.58±0.08	0.131±0.034	
<i>dumerilii</i>						
Fish – emperor						Muscle
<i>Lethrinus</i>	3	Benthic	Carnivorous	4.14±0.18	0.123±0.045	
<i>rubrioperculatus</i>						

*<MDL = arithmetic mean value is <MDL

Sea shells and fish had similar accumulation as sediments as regards pattern of NBFR, mainly due to TBPH and hexabromobenzene being the most abundant NFBRs. No significant relationship between concentration and TL and between concentration and lipid content was observed for TBPH. Using the measured concentrations of TBPH in seawater samples, bioaccumulation factors (BAF) in the marine species were calculated on a lipid weight basis (**Table 17**). These estimated log BAFs range from 2.71 ± 0.39 for crab to 3.62 ± 0.15 for sea shells. BSAFs calculated to predict trophic transfer efficiencies, especially for benthic invertebrates living at the bottom and feeding on sediment particles. The BSAFs for TBPH range from 0.11 ± 0.01 for sea cucumber to 0.86 ± 0.32 for sea shell and 0.86 ± 0.61 for grouper, which indicate that TBPH from sediments is transferred equally to benthic invertebrates as to benthic fish. However, as sediment is not a direct source of TBPH for fish, a major part of the observed bioaccumulation of TBPH come via food chain magnification.

The calculated TMF values for the evaluated NBFRs assess the trophic transfer through the food web and TMF for TBPH was 1.62, which however was not statistically significant. It was the lowest among the studied NBFRs (hexabromobenzene had the highest with a TMF = 5.32).

Table 17: Estimated bioaccumulation and biomagnification factors (log BAFs, BSAFs, and TMFs) for a group of novel brominated flame retardants (NBFR), including TBPH (Hou *et al.*, 2022)

	TBPH	TBP	TBECH	PBT	PBEB	PBP	TBB	HBB	BTBPE	EBP
TMF										
	1.62	1.78	2.08	2.13	2.35	2.79	2.00	5.32	1.91	4.22
Log BAFs/BSAFs										
Sea Shell	3.62/ 0.86	2.48/ 0.67	2.47/ 1.72	2.95/ 2.31	2.90/ 1.87	2.75/ 0.87	3.66/ 0.63	3.52/ 1.31	Nd/ 0.83	4.72/ 1.04
Sea Cucumber	2.76/ 0.11	Nd/ Nd	2.05/ 0.60	2.71/ 1.22	2.32/ 0.40	Nd/ Nd	Nd/ Nd	2.16/ 0.06	Nd/ Nd	3.83/ 0.13
Crab	2.71/ 0.12	2.10/ 0.28	Nd/ Nd	2.32/ 0.50	2.44/ 0.53	2.41/ 0.38	Nd/ Nd	2.10/ 0.05	Nd/ Nd	3.88/ 0.14
Goatfish	3.30/ 0.39	2.60/ 0.90	2.71/ 3.09	3.26/ 4.41	3.05/ 2.22	2.97/ 1.39	3.81/ 0.80	3.73/ 2.11	Nd/ 0.73	5.00/ 1.95
Grouper	3.60/ 0.86	2.61/ 1.14	2.68/ 2.54	3.11/ 2.81	2.98/ 2.59	3.05/ 1.82	3.82/ 0.82	3.92/ 2.90	Nd/ 0.89	5.22/ 2.82
Rabbitfish	3.45/ 0.70	2.61/ 0.89	2.62/ 2.74	2.85/ 1.77	3.11/ 2.06	3.10/ 1.52	3.68/ 0.59	3.56/ 1.32	Nd/ 0.53	4.85/ 1.30
Parrotfish	3.52/ 0.52	2.54/ 0.88	2.69/ 3.16	2.86/ 2.20	2.76/ 1.94	2.88/ 1.31	3.77/ 0.80	3.49/ 1.05	Nd/ 0.84	4.89/ 1.68
Wrasse	3.57/ 0.83	2.84/ 1.42	2.86/ 3.05	3.08/ 3.99	3.27/ 3.17	3.04/ 1.64	3.89/ 1.02	3.38/ 1.77	Nd/ 1.75	5.09/ 2.91
Sweetlips	3.33/ 0.42	2.52/ 0.75	2.33/ 1.22	3.24/ 4.20	3.14/ 2.66	2.98/ 1.42	3.94/ 1.07	3.66/ 1.79	Nd/ 0.99	5.15/ 2.68
Filefish	3.55/ 0.69	2.91/ 1.81	2.44/ 1.58	3.14/ 3.32	3.09/ 2.39	3.08/ 1.80	3.84/ 0.84	3.81/ 2.53	Nd/ 0.92	5.09/ 2.34
Emperor	3.52/ 0.64	2.82/ 1.47	2.59/ 2.21	3.25/ 4.25	3.18/ 2.95	3.15/ 2.11	3.95/ 1.10	4.02/ 4.10	Nd/ 0.85	5.32/ 3.95

Note: TBP = Tribromophenol, TBECH = Tetrabromoethyl cyclohexane, PBT = Pentabromotoluene, PBEB = Petabromoethyl benzene, PBP = Pentabromophenol, TBB = 2-ethylhexyl 2,3,4,5-tetrabromobenzoate, HBB = Hexabromobenzene, BTBPE = 1,2-Bis(2,4,6-tribromophenoxy)ethane, TBPH = bis(2-ethylhexyl)tetrabromophthalate; Nd = Not detected

In order to evaluate the impact of biotransformation rate on bioaccumulation of the NBFRs, the authors performed *in vitro* incubation of the NBFRs in liver microsomes of the fish species *Epinephelus fasciatus* and *Plectorhynchus orientalis* to assess biotransformation clearance rates. The biotransformation of the examined NBFRs followed first-order kinetics in liver microsomes of both fish species. The measured values did not differ significantly between the two species for any of the NBFRs. The *in vitro* biotransformation rates ($CL_{in vitro}$) for TBPH are presented in **Table**

18. The in vitro biotransformation rate for TBPH was, together with HBB, the lowest in sweetlips and the single lowest in grouper. The study is considered reliable, with restrictions.

Table 18: In vitro biotransformation rates for TBPH and other NBRs in liver microsomes from *Epinephelus fasciatus* and *Plectorhynchus orientalis* (Hou et al., 2022)

	Sweetlips		Grouper	
	Clearance rate _{in vitro} (mL/mg protein × h)	r ²	Clearance rate _{in vitro} (mL/mg protein × h)	r ²
TBPH	0.017 ± 0.004	0.803	0.016 ± 0.002	0.964
TBECH	0.067 ± 0.005	0.980	0.061 ± 0.006	0.964
PBT	0.043 ± 0.006	0.938	0.049 ± 0.003	0.981
PBP	0.053 ± 0.005	0.970	0.055 ± 0.004	0.982
TBB	0.065 ± 0.006	0.969	0.053 ± 0.003	0.985
HBB	0.017 ± 0.004	0.968	0.025 ± 0.002	0.980
EBP	0.044 ± 0.002	0.983	0.050 ± 0.001	0.997

There are no estimated biomagnification factors (BMFs) presented in Hou et al. (2022). However, by using the measured concentrations in Hou et al. (2022) and fish feeding habits (Hou et al. 2022 supplementary documentation...), rough BMF estimates (fish/crabs) for the fish species for which crab is indicated as a food source can be calculated (see **Table 19** and **Table 20** below). It is acknowledged that such a BMF gives a very rough indication of the “true” BMF as none of the fish species forage only on crabs. Fish probably constitutes a large part of the prey for some of these fish species whereas sea shells and sea cucumber is not indicated as being a major part of the diet for any of the fish species.

Table 19: Estimated BMFs (fish/crabs) based on measured concentrations of TBPH in Hou et al. (2022) in fish (goatfish and grouper), crabs and fish feeding habit

	Fish - Goatfish			Fish - Grouper			
	<i>Upeneus sulphureus</i>	<i>Parupeneus trifasciatus</i>	<i>Parupeneus barberinus</i>	<i>Epinephelus fasciatus</i>	<i>Variola louti</i>	<i>Cephalopholis argus</i>	<i>Epinephelus merra</i>
Concentration (µg TBPH/kg lw.)	0.090±0.014	0.065±0.008	0.069±0.014	0.118±0.043	0.128±0.068	0.369±0.066	0.083±0.036
Feeding habit	Carnivorous (plankton, shrimp, crab, snail, small fish)	Carnivorous (plankton, shrimp, crab, snail, small fish)	Carnivorous (shrimp, crab, snail, small fish)	Carnivorous (shrimp, crab, snail)	Carnivorous (shrimp, crab, snail, small fish)	Carnivorous (shrimp, crab, snail, small fish)	Carnivorous (shrimp, crab, snail, small fish)
Crabs (average concentration) = 0.0153 (µg TBPH/kg lw.)							
Biomagnification factor (BMF)							
Fish/Crabs	5.9 (=0.090/0.0153)	4.2 (=0.065/0.0153)	4.5 (=0.069/0.0153)	7.7 (=0.118/0.0153)	8.4 (=0.128/0.0153)	24 (=0.369/0.0153)	5.4 (=0.083/0.0153)

Table 20: Estimated BMFs (fish/crabs) based on measured concentrations of TBPH in Hou et al. (2022) in fish (wrasse, sweetlips, filefish and emperor), crabs and fish feeding habit

	Fish - Wrasse		Fish - sweetlips	Fish - filefish	Fish - emperor
	<i>Cheilinus trilobatus</i>	<i>Hemigymnus melapterus</i>	<i>Plectorhynchus orientalis</i>	<i>Cantherhines dumerilii</i>	<i>Lethrinus rubrioperculatus</i>

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Concentration (µg TBPH/kg lw.)	0.081±0.040	0.235±0.109	0.080±0.009	0.131±0.034	0.123±0.045
Feeding habit	Carnivorous (shrimp, crab, snail, small fish)	Carnivorous (shrimp, crab, snail, small fish)	Carnivorous (shrimp, crab, snail, small fish)	Carnivorous (plankton, shrimp, crab, snail, small fish)	Carnivorous (shrimp, crab, snail, small fish)
Crabs (average concentration) = 0.0153 (µg TBPH/kg lw.)					
Biomagnification factor (BMF)					
Fish/Crabs	5.3 (=0.081/0.0153)	15 (=0.235/0.0153)	5.2 (=0.080/0.0153)	8.5 (=0.131/0.0153)	8.0 (=0.123/0.0153)

The estimated BMFs for fish/crabs range from 4.2 – 24 (median = 6.8) and thus indicate that TBPH is biomagnified in fish. It is acknowledged however, that these estimated BMFs are only rough and probably over-estimates potential biomagnification of TBPH as the fish do not forage only on crabs. Adult *Cephalopholis argus* for example feed mainly on fish (75-95%) according to Fish base¹². This species has the highest concentration of TBPH of all the sampled fish species in this study (0.369±0.066 µg TBPH/kg lipid weight) and the second highest value for TL. A BMF based on the average concentration of TBPH in these species and the average concentration of TBPH in all of the sampled fish species (0.129 TBPH/kg lipid weight) results in a BMF of 2.9. This is considered a more realistic estimation of the biomagnification of TBPH in fish. It is acknowledged that there is a large uncertainty also in this BMF value as e.g., the average concentration of TBPH in *Cephalopholis argus* is based only on three individuals. However, taken together the evidence from this study indicate that TBPH is biomagnified in fish.

¹² www.fishbase.se

3.4.4 Summary and discussion of bioaccumulation

With an experimental log Kow of 10.2 TBPH screens as potentially (very) bioaccumulative according to REACH Guidance R.11 and it is not expected to be rapidly absorbed.

Three dietary bioaccumulation studies are available. Only a small part of the total given doses is found in the fish at the end of the exposure period in all three studies. This is probably due to the fact that TBPH is poorly absorbed in the gut of the fish and not because of metabolism and excretion. No difference ($0.0 \pm 4.3\%$) was detected with respect to the concentration of TBPH incubated with active or heat killed common carp (*Cyprinus carpio*) liver microsomes for 2 h at 25°C (n=3). Furthermore, TBPH had among studied NBRs the single lowest *in vitro* biotransformation rate in liver microsomes from the blacktip grouper (*Epinephelus fasciatus*) and the lowest together, with hexabromobenzene, in liver microsomes from the Indian Ocean oriental sweetlips (*Plectorhynchus orientalis*). This indicates that TBPH is very poorly metabolised by fish.

BMFs were measured in two of the studies (Nacci, 2018 and Unpublished, 2018, both studies are reliable with restrictions) and the BMFs were low and of similar magnitude in both studies (**Table 21**). According to REACH Chapter R.11 (ECHA, 2017a), even if a BMF from an OECD TG 305 dietary bioaccumulation study is found to be <1, it cannot be considered as a good discriminator for concluding substances not to be (very) bioaccumulative according to the BCF criteria of Annex XIII.

Table 21: BMF, depuration rate constants and depuration half-lives from the dietary bioaccumulation studies by Nacci (2018) and Unpublished (2018)

	BMF (conc. in fish/conc. in diet)	Depuration rate constant, K2 (day ⁻¹)	Depuration half-life (d)
Nacci (2018)			
High dose	0.005*	0.031*	22*
Low dose	0.02*	0.031*	22*
Unpublished (2018)			
	0.0048*	0.044*	15.6*
Growth corrected	0.0143	0.015	46.2
Growth and lipid corrected	0.0381	-	-

* not growth or lipid corrected

It is important to note that the TBPH concentration in the food was very high in both studies which may have resulted in reduced bioavailability and as a consequence underestimated the BMF value. This is supported by the fact that the BMF at the high dose in the Nacci (2018) study was 4 times lower than in the low dose. The TBPH concentration in the food in the unpublished (2018) study was comparable to the high dose of the Nacci (2018) study. It is therefore plausible that the unpublished (2018) study has underestimated the BMF to some extent. It is not possible to calculate what the growth and lipid corrected BMF in the Nacci (2018) study would be from the information given in the published paper.

Fish BCFs were derived from data generated in the dietary study with rainbow trout (unpublished, 2018) using the 15 models within the OECD TG 305 BCF estimation tool and all BCFs predicted except one (method 3) were above 5000 (see **Figure 1**). All models in method

1 and 2 are based on a predicted uptake rate constant. Considering the low uptake seen in the bioaccumulation studies these methods probably overestimate the uptake rate and thus overestimate the BCF of TBPH. It is also noted that the log K_{ow} of TBPH is higher than the applicability domain of all three methods which according to OECD guidance document 264 (OECD, 2017) is approx. 3.5 – 8.3 for method 1, approx. 3 – 8.2 for method 2 and approx. 4.3 – 9. Furthermore, method 3 was developed from data on Carp (*Cyprinus carpio*) and the applicability for other species is unknown.

On the other hand, the studies indicate that TBPH does not seem to be metabolised by fish with a slow depuration rate (K_2 of 0.031 and 0.044) and very long half-lives in fish (15.6 and 22 days) which could become of a bioaccumulation concern once the substance has entered the food chain. Brooke and Crookes (2012) suggest that a K_2 of 0.085 equals - BCF 5000 and a K_2 of 0.178 equals BCF 2000. Comparing the non-corrected depuration rate constants (**Table 21**) from the two studies with these values indicates that TBPH is very bioaccumulative (BCF > 5000). A benchmark approach comparing laboratory depuration rate constants and BMF values for TBPH and substances identified as SVHC based on their vPvB properties provides further indications that TBPH has vB properties.

Field and biomonitoring data support the above conclusion as they point towards bioaccumulation of TBPH in biota. A TMF study where a TMF of 2.42 for TBPH was derived (Zheng *et al*, 2018), gives support to such a conclusion. Another TMF study by (Hou *et al.*, 2022) also found a positive but in this case not statistically significant relationship between the concentration of TBPH and trophic level. Calculated BMFs based on the data from Hou *et al.* (2022) (fish/crabs, fish/fish) indicate that TBPH is biomagnified in fish. In addition, Jin *et al* (2016) found a correlation between trophic level and TBPH concentration in resident birds of Korea. To this can also be added numerous findings of TBPH in biota including Arctic species such as ringed seal and polar bear. In addition, toxicokinetic studies indicate that despite a low uptake a small fraction of the substance seems to accumulate in tissues (especially adrenal and liver tissue) of the exposed animals. TBPH has also been detected in placentas of rats exposed to TBPH during gestation. Furthermore, TBPH has been detected in plasma and milk of nursing mothers.

Therefore, based on all available information and using a weight-of-evidence approach, it is concluded that TBPH fulfils the very bioaccumulative (vB) criterion set out in REACH Annex XIII (BCF > 5000).

4. Human health hazard assessment

4.1 Toxicokinetics (absorption, metabolism, distribution and elimination)

4.1.1 Non-human information

4.1.1.1 Absorption

Knudsen and co-workers (2017) studied the uptake, distribution, and elimination of TBPH in rats after a single or repeated oral or intravenous administration of ¹⁴C-labeled TBPH. A single dose of ¹⁴C-labeled TBPH was administered to female Sprague Dawley rats by gavage at 0.1 or 10 µmol/kg (n = 4/dose group) to examine dose effects. The results of this study indicated poor absorption of TBPH after gavage administration. Studies of repeated oral exposures showed that while only a small amount of TBPH is absorbed, it has the potential to accumulate in adrenal and liver tissue, largely as the parent substance.

Fang *et al.* (2014) evaluated the bioavailability of 20 halogenated flame retardants (HFR), including TBPH, in HFR-laden house dust Standard Reference Material (SRM) 285 and 17 house dust samples using an *in vitro* Tenax bead-assisted sorptive method. Using Tenax beads and simulated digestive fluids Fang and co-workers observed 29% bioaccessibility for TBPH. The bioavailability results for several PBDEs, which was also evaluated in this study, were in close agreement with results from an *in vivo* rat exposure study using indoor dust.

4.1.1.2 Metabolism

The available studies indicate that TBPH are poorly metabolised. The hydrolysis metabolite mono(2-ethylhexyl) tetrabromophthalate has been identified *in vitro* after addition of porcine hepatic carboxylesterase (Roberts *et al.*, 2012) and tetrabromo phthalic acid has been detected in rat serum and urine at low levels after administration via gavage (Silva *et al.*, 2015).

Metabolism of TBPH has been studied *in vitro*, using rat liver and intestinal subcellular fractions (Roberts *et al.*, 2012). No significant loss of TBPH was observed and no metabolites were detected in experiments with rat liver microsomes.

In vivo, metabolism of TBPH was studied in female rats exposed to the flame retardant Uniplex FRP-45 (Silva *et al.*, 2015). Animals were administered 500 mg/kg Uniplex FRP-45 (>95% TBPH) by gavage. No TBPH or oxidative metabolites similar to those formed by DEHP were found in serum or urine after 24h. Tetrabromo phthalic acid (TBPA) was identified as a urinary and serum metabolite at low levels. The mean urinary levels were ca. 0.5 mg/L and mean serum levels ca. 0.05 mg/L. Tetrabromobenzoic acid (TBBA), the metabolite of 2-ethylhexyl tetrabromobenzoate (TBB) was detected at concentrations much higher (ca. 100 times in urine and ca. 25 times in serum) than TBPA, even though TBB was only a minor constituent (< 5%) in the mixture. The study authors hypothesised that because of its relatively low solubility and high molecular weight, TBPH may be excreted unchanged via faeces.

4.1.1.3 Distribution and elimination

A study was conducted in rats and mice (Knudsen *et al.*, 2017). A single dose of ¹⁴C-labeled TBPH was administered to female Sprague Dawley rats by gavage at 0.1 or 10 µmol/kg (n = 4/dose group) to examine dose effects. Male mice (B6C3F1/Tac) were dosed a single gavage dose of 0.1 µmol/kg. To determine the fate of systemically available TBPH, a single intravenous (IV) bolus (0.1 µmol/kg) was injected into the lateral tail vein of female rats. Bioaccumulation

potential in female SD rats was assessed by examining [¹⁴C]-radioactivity recoveries in excreta and tissues collected 24 h after 10 daily oral administrations of TBPH (0.1 µmol/kg, n = 4).

In rats approximately 75% of the administered dose was recovered in faeces and less than 0.3% in urine after 24 h, with negligible difference between the doses. After 72 h rats had eliminated 92–98% of TBPH unchanged in faeces and 0.8–1% in urine. [¹⁴C]-radioactivity retained in tissues collected at 72 h following oral administration was low (~1% of total dose in assayed tissues). The disposition of TBPH in male mice and female rats was similar.

Recovery 72 h after IV administration reached 78% in faeces and 1.3% in urine. About 20% of the IV-administered TBPH was retained in tissues with 7% in liver, 5% in muscle, 3% in skin, 2% in fat and 1% in the adrenal gland. Faeces collected after IV dosing appeared to contain a mixture of parent (~30%) and metabolites mono-(2-ethylhexyl)tetrabromophthalate (TBMEHP~70%).

Similar to a single dose, repeated administration of TBPH resulted in a small amount of the total dose excreted in urine and the majority in faeces. Total elimination was determined at 24 h intervals and compared to elimination from animals administered a single dose. Bioaccumulation was observed in liver and adrenals following 10 daily oral administrations. Significantly more TBPH was present in liver after 10 doses (113 ± 16 pmol-eq/g) than after one (23 ± 4 pmol-eq/g). Concentrations in adrenal tissue increased more than 10-fold after 10 doses (see **Table 22**).

Table 22: [¹⁴C]-radioactivity in selected tissues of rats 24 hours following a single oral dose of TBPH (0.1 µmol/kg) or 24 hours after the final dose of 10 repeated oral doses of 0.1 µmol/kg /day (Knudsen *et al.*, 2017).

Tissue	Dose recovered (%)		Concentration (pmol-eq/g)	
	1 dose	10 doses	1 dose	10 doses
Feces	91 ± 11	100 ± 5	-	-
Urine	0.3 ± 0.1	0.6 ± 0.1	-	-
Adipose	0.3 ± 0.1	0.6 ± 0.1	4 ± 5	8 ± 7
Adrenal	0.4 ± 1	0.04 ± 0.1	20 ± 5	207 ± 142
Kidney	0.01 ± 0.003	0.01 ± 0.004	1 ± 1	3 ± 1
Liver	0.01 ± 0.01	0.002 ± 0.001	23 ± 4	113 ± 16
Skin	1 ± 0.2	0.4 ± 0.09	1 ± 1	3 ± 1

The results of this study indicate poor absorption of TBPH after gavage administration. Studies of repeated oral exposures showed that while only a small amount of TBPH is absorbed, it has the potential to accumulate in adrenal and liver tissue, largely as the parent substance.

Baldwin *et al.* (2017) exposed Wistar rats (N=24) to FM 550 for 10 days during gestation (GD 9-18). The rats were exposed to either 0 µg, 300 µg or 1000 µg FM 550 via the feed producing exposures of approximately 0, 1 and 3.3 mg/kg bw per day. FM 550 is a TBPH/TBB/organophosphate mixture with the ratio TBPH+TBB: organophosphates - 50:50. The TBPH:TBB ratio in the mixture is approx. 20-30:70-80. Based on these relationships the TBPH exposure in the low and high dose can be calculated to approx. 30-40µg (0.1 mg/kg bw/day) and 100 – 130 µg (0.33 mg/kg bw/day), respectively.

The rats were sacrificed on GD 18, four hours after final dosing. TBPH, TBB, and organophosphates were analysed in homogenised whole placenta (6 per sex per group). The TBPH:TBB ratio in the placentas was similar to the TBPH:TBB ratio in FM 550. The results excluding the organophosphates are presented in **Table 23**.

Table 23: Concentration of TBPH and TBB in placenta associated to male or female fetuses of rats exposed to the flame retardant formulation FM 550 (Baldwin *et al.*, 2017).

	Substance	Exposure FM 550 (mg/kg bw per day)					
		0		1		3.3	
		Male	Female	Male	Female	Male	Female
Conc. in placenta (µg/kg ww)	TBPH	N.D.	N.D.	10.8 ± 1.2	8.9 ± 0.5	31.5 ± 2.4	26.8 ± 1.3
	TBB	N.D.	N.D.	25.3 ± 4.8	21.2 ± 3.6	86.1 ± 15.9	105.5 ± 12.5

N.D. = Not detected

4.1.2 Human information (including bioaccumulation in humans)

4.1.2.1 Metabolism

Metabolism of TBPH has been studied *in vitro* using human liver and intestinal subcellular fractions (Roberts *et al.*, 2012). No significant loss of TBPH was observed and no metabolites were detected in experiments with human liver microsomes. Mono(2-ethylhexyl) tetrabromophthalate (TBMEHP), a hydrolysis metabolite of TBPH, was slowly formed when porcine hepatic carboxylesterase was added to the assay. In a previous study, metabolism of DEHP to its toxic metabolite mono(2-ethylhexyl) phthalate (MEHP) was measured to be at a rate approximately 100 times faster than the hydrolysis of TBPH to TBMEHP (Niino *et al.*, 2003).

4.1.2.2 Levels of TBPH in human body fluids

4.1.2.2.1 Exposure

Flame retardants are common additives used in construction materials and consumer products and these additives will over time migrate out of the materials and many flame retardants will end up in house dust (Fang and Stapleton, 2014). Flame retardants in dust may originate from a number of different sources, e.g., sorbed to organic material following partitioning from air or be associated with debris in dust resulting from product weathering (Fang and Stapleton, 2014). Ingestion of house dust have been identified as one of the most important exposure pathways for flame retardants, especially for infants and toddlers (Johnson *et al.*, 2010; Stapleton *et al.*, 2012).

4.1.2.2.2 General population

He *et al.* (2013) analysed serum from 305 residents in the Laizhou bay area, in the north-eastern China, which is a production area for halogenated flame retardants. All of the volunteers lived within 10 km of the main chemical production sites and had no liver disease. The volunteers were residents and some of them have been factory workers. The samples were pooled in 10 groups (5 age groups/gender: 20-29, 30-39, 40-49, 50-59 and >60). TBPH was detected in females in the age group 30-39 years at a concentration of 260 µg TBPH/kg lw. but not in the other four female age groups and not in males.

Chen *et al.* (2019) measured flame retardants, including TBPH, in 50 paired human fingernails and indoor dust samples collected from resident houses (n = 27) in Nanjing, China as well as

undergraduate/graduate student dormitories (n = 23) in Nanjing University, Xianlin Campus, during June-September 2016. The participants were asked to wash their hands before clipping fingernails of ten fingers with a stainless-steel nail clipper. None of the participants worked in the production of flame retardants or flame retardant related products. The measured concentrations of TBPH in fingernails ranged from 4.21 - 689 µg TBPH/kg (median = 28.1 µg TBPH/kg; detection frequency 100%). There was a significant positive correlation between TBPH in fingernails and indoor dust (p<0.001, r=0.37) which indicate that indoor dust plays an important part in the exposure of TBPH via pathways such as dust ingestion/inhalation and dust contact.

4.1.2.2.3 Gestational and lactational transfer

Zhou *et al.* (2014) analysed several brominated flame retardants including TBPH in paired human maternal serum (n = 102) and breast milk (n = 105) collected in the Sherbrooke region in Canada 2008-2009. The detection frequency for TBPH in serum was 16.7% (LOD 7.3 µg TBPH/kg lipid weight) and in milk 32.4% (LOD 0.15 µg TBPH/kg lipid weight). The concentrations in serum ranged from ND to 164 µg TBPH/kg lipid weight and in milk from ND to 6.6 µg TBPH/kg lipid weight.

4.1.3 Conclusion on toxicokinetics (and bioaccumulation in humans)

The available toxicokinetic data indicate that TBPH is poorly absorbed and poorly metabolised and is mainly excreted unchanged via faeces after oral exposure. However, a small fraction of the substance seems to be accumulating in tissues of the exposed organisms.

Studies of repeated oral exposures showed that while only a small amount of TBPH is absorbed, it has the potential to accumulate in adrenal and liver tissue, largely as the parent substance. Seventy-two hours after intravenous administration the majority of TBPH is excreted via faeces as a mixture of parent and the metabolite TBMEHP. Of the TBPH absorbed after IV-administration most was retained in liver, followed by muscle, skin, fat and adrenal gland, respectively.

TBPH has been detected in plasma and breast milk of nursing women.

5. Environmental hazard assessment

The available toxicity data (environmental as well as mammalian) indicates that TBPH does not fulfil the T-criterion of REACH Annex XIII. However, this information is considered to be not relevant for the identification of the substance as SVHC in accordance with Article 57 (e).

6. Conclusions on the SVHC Properties

6.1 CMR assessment

Not relevant for the identification of the substance as SVHC in accordance with Article 57 (e) of the REACH Regulation.

6.2 PBT and vPvB assessment

6.2.1 Assessment of PBT/vPvB properties

Bis(2-ethylhexyl) tetrabromophthalate is a diastereoisomer consisting of three stereoisomers. There is experimental information available for the whole substance, but not for the single constituents. The diastereoisomers have the same molecular formula and sequence of bonded elements and differ only in the 3D representation of the structure. That is why based on their chemical structure and in line with the PBT guidance (REACH Chapter R.11, 2017), the three isomers are expected to behave similarly in the environment and the whole substance approach can be reasonably assumed. As the isomers are structurally similar, they can be expected to have a reasonably similar vPvB-properties as the whole substance.

Furthermore, the low degradation observed in the screening tests (<8 % of degradation) and the absence of degradation of the whole substance in the sediment mesocosm study support the conclusion that the three isomers have similar vP properties as the whole substance.

As regards the bioaccumulation potential, from the available data on the whole substance there is no indication that it can be metabolised or biotransformed significantly thus supporting the evidence that the isomers are predicted to have vB properties.

A weight-of-evidence determination according to the provisions of Annex XIII of REACH is used to identify the substance and its isomers as vPvB. All available relevant information (such as the results of standard tests, monitoring and modelling, information from the application of the category and analogue approach (grouping, read-across) and (Q)SAR results) was considered together in a weight-of-evidence approach.

6.2.1.1 Persistence

The information available on hydrolysis is difficult to interpret considering contradicting results. However, due to its low solubility and high Koc TBPH is expected to sorb to particles and to mainly distribute to sediment in the aquatic environment. Hydrolysis is expected to be hindered by adsorption potential of TBPH onto sediment and particulate matter. Therefore, hydrolysis is not considered to be a relevant degradation mechanism for TBPH. AOPWIN v1.92 predicts that TBPH has an atmospheric half-life of 5.8 hours in the gas-phase and it is degraded by sunlight when dissolved in different organic solvents. However, TBPH has a very low vapour pressure and is mainly distributed to the particulate phase of the atmosphere. This is confirmed by air monitoring data, also in the air of remote areas proving the Long-range transport potential of

TBPH via air. Photodegradation in the atmosphere is therefore also not considered to be a relevant removal process for TBPH.

BIOWIN predictions (low reliability) indicate that TBPH screens as potentially persistent or very persistent and this has also been demonstrated in screening studies where very little degradation was observed. Furthermore, results from an inherent degradation test (reliable with restrictions) performed according to OECD guideline 302C (7% degradation in 28 days) indicates that TBPH is persistent. REACH guidance R.11 (ECHA, 2017) states that a "*Lack of degradation (<20% degradation) in an inherent biodegradability test equivalent to the OECD TG 302 series may provide sufficient information to confirm that the P-criteria are fulfilled without the need for further simulation testing for the purpose of PBT/vPvB assessment. Additionally, in specific cases it may be possible to conclude that the vP-criteria are fulfilled with this result if there is additional specific information supporting.*

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. Many conditions (high temperature compared to EU standard conditions, pre-exposure of micro-organisms to test conditions and exposure to sunlight leading to abiotic degradation (photolysis)) 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.

	Annex XIII	TBPH	Conclusion
P/vP	<p>P</p> <p>Half life:</p> <p>a) in marine water > 60 days, or</p> <p>b) in fresh- or estuarine water > 40 days, or</p> <p>c) in marine sediment > 180 days, or</p> <p>d) in fresh- or estuarine sediment > 120 days, or</p> <p>e) in soil > 120 days</p> <p>vP</p> <p>Half life:</p>	<p>Results from an inherent degradation test performed according to OECD guideline 302C (7% degradation in 28 days).</p> <p>A DT₅₀>200 d for sediment from a non-guideline outdoor mesocosm study.</p> <p>The presence of TBPH in all environmental compartments including air, surface water, sediment, and biota, including remote regions such as the Tibetan Plateau and the Arctic.</p>	vP

	a) in marine, fresh- or estuarine water > 60 days, or b) in marine, fresh- or estuarine sediment > 180 days, or c) in soil > 180 days		
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6.2.1.2 Bioaccumulation

With a log Kow of 10.2 TBPH screens as potentially (very) bioaccumulative according to REACH Guidance Chapter R.11 (ECHA, 2017) and it is not expected to be readily absorbed. This is confirmed by toxicokinetic studies showing that a major part of a given dose is excreted unchanged. However, a small fraction of the substance is absorbed and accumulates in tissues of the exposed organisms. That TBPH is taken up by biota is confirmed by monitoring data.

In the available fish dietary bioaccumulation studies only a small part of the total given doses of TBPH was found in the fish at the end of the uptake period. This is probably due to that TBPH is poorly absorbed in the gut of the fish and not because of metabolism and excretion. No difference was detected with respect to the concentration of TBPH incubated with active or heat killed common carp (*Cyprinus carpio*) liver microsomes. Furthermore, TBPH had among studied NBFRs the single lowest *in vitro* biotransformation rate in liver microsomes from the Blacktip grouper (*Epinephelus fasciatus*) and the lowest together, with hexabromobenzene, in liver microsomes from the Indian Ocean oriental sweetlips (*Plectorhynchus orientalis*). Also, this indicating that TBPH is very poorly metabolised by fish. BMFs were measured in two of the fish dietary bioaccumulation studies (reliable with restrictions). The BMFs were low and of similar magnitude in both studies (0.02 for Atlantic killifish, (*Fundulus heteroclitus*) and 0.038 for Rainbow trout (*Oncorhynchus mykiss*). According to REACH Chapter R.11 (ECHA, 2017), even if a BMF from an OECD TG 305 dietary bioaccumulation study is found to be <1, it cannot be considered as a good discriminator for concluding substances not to be (very) bioaccumulative according to the BCF criteria of Annex XIII. Furthermore, it is important to note that the TBPH concentration in the food was very high in both studies which may have resulted in reduced bioavailability and as a consequence underestimated the BMF values.

Fish BCFs were derived from data generated in the dietary study with rainbow trout (unpublished, 2018) using the 15 models within the OECD TG 305 BCF estimation tool and all BCFs predicted except one (method 3) were above 5000. However, most of the models are based on a predicted uptake rate constant which considering the low uptake seen in the bioaccumulation studies may be overestimated, thus overestimating the BCF of TBPH. It is also noted that, according to the OECD guidance document on aspects of OECD TG 305 (OECD 2017), the log Kow of TBPH (10.2) is higher than the applicability domain of all these models. Furthermore, the model where a BCF < 2000 was derived was developed from data on Carp (*Cyprinus carpio*) and the applicability for other species is unknown. On the other hand, the studies indicate that TBPH is poorly metabolised by fish with slow depuration rates (K_2 of 0.031 and 0.044) and very long half-lives in fish (15.6 and 22 days) which could become of a bioaccumulation concern once the substance has entered the food chain. Comparing the non-corrected depuration rate constants from the dietary bioaccumulation studies with the criteria proposed by Brooke and Crookes, 2012 (K_2 of 0.085 equals - BCF 5000 and a K_2 of 0.178 equals BCF 2000) indicates that TBPH is very bioaccumulative, i.e., has a BCF>5000. A benchmark approach comparing laboratory depuration rate constants and BMF values for TBPH and substances identified as SVHC based on their vPvB properties provides further indications that TBPH has vB properties.

Field and biomonitoring data support the above conclusion as they point towards bioaccumulation of TBPH in biota. A TMF of 2.42 for TBPH has been measured in a limnic food

SVHC SUPPORT DOCUMENT - BIS(2-ETHYLHEXYL) TETRABROMOPHTHALATE COVERING ANY OF THE INDIVIDUAL ISOMERS AND/OR COMBINATIONS THEREOF

chain study from China, indicating trophic magnification. A TMF of 1.62, however not significant, in a marine food chain study from China points in the same direction. Tentative BMFs based on the data from Hou *et al.* (2022) (fish/crabs, fish/fish), although uncertain, indicate that TBPH is biomagnified in fish. In addition, a positive correlation between trophic level and TBPH concentration has been found in resident predatory birds of Korea. Finally, the ubiquitous presence of TBPH in biota (mussel, fish, birds, mammals (including in human serum)) also in arctic species such as ringed seal and polar bear and that it is transferred from human mothers to their babies via breast milk gives further indication that TBPH is very bioaccumulating.

Based on the weight-of-evidence of the data available, it is therefore considered that TBPH fulfils the vB criterion of REACH Annex XIII (BCF > 5000).

	Annex XIII	TBPH	Conclusion
B/vB	<p>(a)</p> <p>B</p> <p>BCF in aquatic species > 2000</p> <p>vB</p> <p>BCF in aquatic species > 5000</p> <p>(b) Other information on the bioaccumulation potential provided that its suitability and reliability can be reasonably demonstrated, such as:</p> <ul style="list-style-type: none"> · Results from a bioaccumulation study in terrestrial species; · Data from scientific analysis of human body fluids or tissues, such as blood, milk, or fat; · Detection of elevated levels in biota, in particular in endangered species or invulnerable populations, compared to levels in their surrounding environment; · Results from a chronic toxicity study on animals; · Assessment of the toxicokinetic behaviour of the substance; <p>(c) Information on the ability of the substance to biomagnify in the food chain, where possible expressed by biomagnification factors or trophic magnification factors.</p>	<p>Comparing the non-corrected depuration rate constants from the dietary bioaccumulation studies (0.031/0.031, 0.044) with the criteria proposed by Brooke and Crookes, 2012 (K2 of 0.085 equals - BCF 5000 and a K2 of 0.178 equals BCF 2000) suggests that TBPH is very bioaccumulative, i.e. has a BCF>5000. This is further supported by a benchmark approach comparing laboratory depuration rate constants and BMF values for TBPH and substances identified as SVHC based on their vPvB properties.</p> <p>A TMF of 2.42 for TBPH measured in a limnic food chain study from China. A TMF of 1.62, however not significant, measured in a marine food chain study from China.</p> <p><i>In vitro</i> data on biotransformation rate of TBPH in liver microsomes from fish indicate that TBPH is very poorly metabolised in fish.</p> <p>Indications of biomagnification in fish in a marine food web study from China.</p> <p>A positive correlation between trophic level and TBPH concentration in resident predatory birds of Korea.</p> <p>A ubiquitous presence of TBPH in biota (mussel, fish, birds, mammals) including arctic species such as ringed seal and polar bear.</p> <p>TBPH is transferred from human mothers to their babies via breast milk.</p>	vB

6.2.1.3 Toxicity

The available toxicity data (environmental as well as mammalian) indicates that TBPH does not fulfil the T-criterion of REACH Annex XIII.

	Annex XIII	TBPH	Conclusion
T	a) NOEC < 0.01 mg/L, or b) meets the criteria for classification as carcinogenic (cat. 1A or 1B), germ cell mutagenic (cat. 1A or 1B), or toxic for reproduction (cat. 1A, 1B, 2), or c) meets the criteria for classification as STOT RE (cat. 1 or 2).	The available toxicity data (environmental as well as mammalian) indicates that TBPH does not fulfil the T-criterion of REACH Annex XIII.	Not T

6.2.2 Summary and overall conclusions on the PBT and vPvB properties

Bis(2-ethylhexyl) tetrabromophthalate is a diastereoisomer consisting of three stereoisomers. There is experimental information available for the whole substance, but not for the single constituents. The diastereoisomers have the same molecular formula and sequence of bonded elements and differ only in the 3D representation of the structure. That is why based on their chemical structure and in line with the PBT guidance, the three isomers are expected to behave similarly in the environment and the whole substance approach can be reasonably assumed. 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.

A weight-of-evidence determination according to the provisions of Annex XIII of REACH is used to identify the substance and its isomers as vPvB. All available relevant information (such as the results of standard tests, monitoring and modelling, and (Q)SAR results) was considered together in a weight-of-evidence approach.

Persistence

The information available on hydrolysis is difficult to interpret considering contradicting results. However, due to its low water solubility and high K_{oc}, TBPH is expected to sorb to particles and to mainly distribute to sediment in the aquatic environment. Hydrolysis is expected to be hindered by adsorption potential of TBPH onto sediment and particulate matter. Therefore, hydrolysis is not considered to be a relevant degradation mechanism for TBPH.

AOPWIN v1.92 predicts that TBPH has an atmospheric half-life of 5.8 hours in the gas-phase and it is degraded by sunlight when dissolved in different organic solvents. However, TBPH has a very low vapour pressure, and it is predicted to distribute mainly to the particulate phase of the atmosphere. The sorbed fraction is likely to be resistant to atmospheric oxidation. This is confirmed by air monitoring data (including from remote areas), thus indicating the long-range transport potential of TBPH via air. Photodegradation in the atmosphere is therefore not considered to be a relevant removal process for TBPH.

BIOWIN predictions (low reliability) indicate that TBPH screens as potentially persistent (P) or very persistent (vP) and this is supported by screening studies where very little degradation was observed for TBPH. Furthermore, results from an inherent degradation test (reliable with restrictions) performed according to OECD guideline 302C (7% degradation in 28 days) indicate that TBPH is persistent. It is worth noting that REACH guidance R.11 states "*Lack of degradation (<20% degradation) in an inherent biodegradability test equivalent to the OECD TG 302 series may provide sufficient information to confirm that the P-criteria are fulfilled without the need for further simulation testing for the purpose of PBT/vPvB assessment. Additionally, in specific cases it may be possible to conclude that the vP-criteria are fulfilled with this result if there is additional specific information supporting.*"

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. 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. Many conditions (high temperature compared to EU standard conditions, pre-exposure of micro-organisms to test conditions and exposure to sunlight leading to abiotic degradation (photolysis)) 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.

Bioaccumulation

With an experimental log K_{ow} of 10.2 TBPH screens as potentially (very) bioaccumulative according to REACH Guidance Chapter R.11 and it is not expected to be rapidly absorbed. This is confirmed by toxicokinetic studies showing that a major part of a given dose is excreted unchanged. However, a small fraction of the substance is absorbed and accumulates in tissues of the exposed organisms. This is confirmed by monitoring data which indicate an uptake of TBPH by biota.

In the available fish dietary bioaccumulation studies only a small part of the total given doses of TBPH were found in the fish at the end of the uptake period. This is probably because TBPH is poorly absorbed in the gut of the fish and not because of metabolism and excretion. No difference was detected with respect to the concentration of TBPH incubated with active or heat killed common carp (*Cyprinus carpio*) liver microsomes. Furthermore, TBPH had among studied Novel brominated flame retardants (NBFRs) the single lowest *in vitro* biotransformation rate in liver microsomes from the Blacktip grouper (*Epinephelus fasciatus*) and the lowest together, with hexabromobenzene, in liver microsomes from the Indian Ocean oriental sweetlips (*Plectorhynchus orientalis*). This also indicates that TBPH is very poorly metabolised by fish.

BMFs were measured in two of the fish dietary bioaccumulation studies (reliable with restrictions). The BMFs were of similar magnitude in both studies (0.02 for Atlantic killifish, (*Fundulus heteroclitus*) and 0.038 for rainbow trout (*Oncorhynchus mykiss*). It is important to note that the TBPH concentration in the food was very high in both studies which may have resulted in reduced bioavailability and as a consequence underestimated the BMF values. Fish

BCFs were derived from data generated in the dietary study with rainbow trout using the 15 models within the OECD TG 305 BCF estimation tool and all BCFs predicted except one (method 3) were above 5000. It is worth noting that these calculated BCFs have some uncertainties considering: a possible overestimation of the uptake rate constant (k_1) estimated by the models thus leading to an overestimation of the BCFs; a high log K_{ow} for TBPH (10.2) which is higher than the applicability domain of the 15 models; the model where a BCF < 2000 (method 3) was developed from data on Carp (*Cyprinus carpio*) while the applicability for other species is unknown. However, the studies indicate that TBPH is poorly metabolised with slow depuration rates (K_2 of 0.031 and 0.044) and very long half-lives in fish (15.6 and 22 days) which could become of a bioaccumulation concern once the substance has entered the food chain. Indeed, the comparison of the non-corrected depuration rate constants (K_2) from the dietary bioaccumulation studies (0.031 and 0.044) with the criteria proposed by Brooke and Crookes, 2012 (K_2 of 0.085 equals - BCF 5000 and a K_2 of 0.178 equals BCF 2000) indicates that TBPH is very bioaccumulative, i.e., has a BCF > 5000. A benchmark approach comparing laboratory depuration rate constants and BMF values for TBPH and substances identified as SVHC based on their vPvB properties provides further indications that TBPH has vB properties.

Other information in accordance with REACH Annex XIII points 3.2.2 (b) and (c) such as field and biomonitoring data support the above conclusion as they point towards bioaccumulation of TBPH in biota. A TMF of 2.42 for TBPH has been measured in a limnic food chain study from China, indicating trophic magnification. A TMF of 1.62 in a marine food chain study from China points in the same direction (although not statistically significant). Tentative BMFs (fish/crabs, fish/fish), although uncertain, indicate that TBPH is biomagnified in fish. In addition, a positive correlation between trophic level and TBPH concentration has been found in resident predatory birds of Korea. Finally, the ubiquitous presence of TBPH in biota (mussel, fish, birds, mammals (including in human plasma)) also in Arctic species such as ringed seal and polar bear (an endangered species) and the transfer of TBPH from human mothers to their babies via breast milk gives further indication that TBPH is very bioaccumulative.

Based on the weight-of-evidence of the data available and considering assessment information in accordance with REACH Annex XIII points 3.2.2 (a), (b) and (c), it is concluded that TBPH fulfils the vB criterion of REACH Annex XIII (BCF > 5000).

Conclusion

Based on the information available, it is concluded that bis(2-ethylhexyl) tetrabromophthalate and its isomers meet the criteria for a vPvB substance in accordance with Annex XIII of the REACH Regulation, and thereby they fulfil the criteria set out in REACH Article 57 (e).

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Annex I – Environmental and human monitoring data

Table 24: TBPH levels in air

Location	Year(s)	n	% Detect	Range (pg TBPH/m ³)	Mean ± SD (pg TBPH/m ³)	Geometric Mean (GM)/Median (pg TBPH/m ³)	Reference
Urban areas							
Canada Toronto	2010 - 2011	70	87			Median = 0.26	Shoeib <i>et al.</i> , 2014
China Harbin	2008 - 2013	227					Li <i>et al.</i> , 2016
-Gas			16	<1.04 - 23	1.1 ± 2.2	Median= <1.04	
-Particle			75	<1.04 - 2600	29 ± 200	Median = 4.3	
-Gas + part.			75	<1.04 - 2600	30 ± 200	Median = 5.3	
Denmark Copenhagen	2009	1	100	0.31	0.31	Median = 0.31	Schlabach <i>et al.</i> , 2011
Norway Oslo (outdoor)	2009	2	100	0.42 - 1.7	1.1 ± 0.91	Median = 1.1	Schlabach <i>et al.</i> , 2011
Oslo (indoor)		3	100	6.7 - 7.4	7.1 ± 0.35	Median = 7.1	

SVHC SUPPORT DOCUMENT - BIS(2-ETHYLHEXYL) TETRABROMOPHTHALATE COVERING ANY OF THE INDIVIDUAL ISOMERS AND/OR COMBINATIONS THEREOF

Location	Year(s)	n	% Detect	Range (pg TBPH/m ³)	Mean ± SD (pg TBPH/m ³)	Geometric Mean (GM)/Median (pg TBPH/m ³)	Reference
Norway Oslo (outdoor)	2019	7	40	<0.6 – 2.88 pg/day	1.12 pg/day	Passive air samples; Median = 0.3*	NILU, 2020
Sweden Stockholm	2009 - 2010	2	50	<0.44 – 0.34	0.28* ± 0.085*	Median = 0.28*	Schlabach <i>et al.</i> , 2011
USA Chicago	2008 - 2010	86	93	0.36 - 76	6.2 ± 1.2	GM = 3.1	Ma <i>et al.</i> , 2012
Cleveland		76	99	0.47 - 290	14 ± 5	GM = 3.8	
USA Chicago	2005 - 2013	~1300	85			GM = 3.4 Median = 3.6	Liu <i>et al.</i> , 2016
Cleveland			83			GM = 4.1 Median = 3.7	
Rural areas							
Denmark Lille Valby	2009	1	100	0.32	0.32	Median = 0.32	Schlabach <i>et al.</i> , 2011
Sweden Råö	2009 - 2010	2	0	<0.74 - <0.78	0.38* ± 0.01*	Median = 0.38*	Schlabach <i>et al.</i> , 2011
Uganda Lake	2008	9	0		BDL (<0.69)	GM = BDL Median = BDL	Arinaitwe <i>et al.</i> , 2014

SVHC SUPPORT DOCUMENT - BIS(2-ETHYLHEXYL) TETRABROMOPHTHALATE COVERING ANY OF THE INDIVIDUAL ISOMERS AND/OR COMBINATIONS THEREOF

Location	Year(s)	n	% Detect	Range (pg TBPH/m ³)	Mean ± SD (pg TBPH/m ³)	Geometric Mean (GM)/Median (pg TBPH/m ³)	Reference
Victoria at Entebbe	2009	30	17		3.39	GM = BDL Median = BDL	
	2010	17	88		18.2	GM = 11.0 Median = 17.0	
USA	2008 - 2010						Ma <i>et al.</i> , 2012
Eagle Harbor		100	61	0.13 - 32	1.1 ± 0.5	GM = 0.42	
Sleeping Bear Dunes		100	49	0.11 - 16	1.1 ± 0.4	GM = 0.45	
Sturgeon Point		95	73	0.14 - 17	0.90 ± 0.24	GM = 0.52	
Point Petre		45	53	0.18 - 3.7	0.79 ± 0.19	GM = 0.53	
USA	2005 - 2013	~1300					Liu <i>et al.</i> , 2016
Eagle Harbor			69			GM = 0.53 Median = 0.47	
Sleeping Bear Dunes			63			GM = 0.46 Median = 0.39	
Sturgeon Point			75			GM = 0.58 Median = 0.51	
Remote areas							
Canada	2006-2007						Xiao <i>et al.</i> , 2012
Alert -							

SVHC SUPPORT DOCUMENT - BIS(2-ETHYLHEXYL) TETRABROMOPHTHALATE COVERING ANY OF THE INDIVIDUAL ISOMERS AND/OR COMBINATIONS THEREOF

Location	Year(s)	n	% Detect	Range (pg TBPH/m ³)	Mean ± SD (pg TBPH/m ³)	Geometric Mean (GM)/Median (pg TBPH/m ³)	Reference
(Canadian High Arctic)		14	21	0.13 – 1.5	0.8	Median = 0.69	
Canada Yukon territory, Little Fox Lake	2011-2014	42	38	0.028 – 5.55	0.86	Median = 0.353	Yu <i>et al.</i> , 2015
East China sea – High Arctic	2010						Möller <i>et al.</i> , 2011b
-Gas		17	0.24	<0.16 – 3.4	0.43 ± 0.88	Median = 0.08	
-Particle		16	25	<0.16 – 0.54	0.13 ± 0.12	Median = 0.08	
East Greenland sea	2009						Möller <i>et al.</i> , 2011a
-Particle		10	40	<0.009 – 0.08	0.01 ± 0.02	Median = 0.0045*	
Indian ocean-Southern ocean	2010-2011						Möller <i>et al.</i> , 2012
-Particle		20	90	<0.025 – 2.8	0.62 ± 0.41	Median = 0.22	
Norway Svalbard	2012-2013	34	88	0.27-14	2.7 ± 0.49	Median = 1.8	Salamova <i>et al.</i> , 2014

SVHC SUPPORT DOCUMENT - BIS(2-ETHYLHEXYL) TETRABROMOPHTHALATE COVERING ANY OF THE INDIVIDUAL ISOMERS AND/OR COMBINATIONS THEREOF

Location	Year(s)	n	% Detect	Range (pg TBPH/m ³)	Mean ± SD (pg TBPH/m ³)	Geometric Mean (GM)/Median (pg TBPH/m ³)	Reference
Tibet Nam Co (Tibetan plateau)	2006-2007	15	53	0.049 – 1.7	0.38	Median = 0.27	Xiao <i>et al.</i> , 2012

*In case of values <Limit Of Quantification or <Method Detection Limit, ½ value will be used
 GM = Geometric Mean
 BDL = Below detection Limit

Table 25: TBPH levels in indoor dust

Location	Year(s)	n	% detect	Range (µg TBPH/kg)	Mean ± SD (µg TBPH/kg)	Geometric Mean/Median (µg TBPH/kg)	Reference
USA Seattle -Gymnasium Inhalable (> 4 µm) Respirable (< 4 µm) -Residence (Coaches) Inhalable (> 4 µm)		4	100 75 75	4.90 – 71.9 nd – 12.8 nd – 18.3	34.3 5.41 8.61		La Guardia <i>et al.</i> , 2017

SVHC SUPPORT DOCUMENT - BIS(2-ETHYLHEXYL) TETRABROMOPHTHALATE COVERING ANY OF THE INDIVIDUAL ISOMERS AND/OR COMBINATIONS THEREOF

Respirable (< 4 µm)			50	nd - 18.6	6.93		
-Residences/ Offices							
Inhalable (> 4 µm)		10					
Respirable (< 4 µm)			20	nd - 25.6	2.97		
			50	nd - 3.44	0.57		
China	2014						Sun <i>et al.</i> , 2018
Hangzhou							
-Home		20	100	0.1 - 54.2	15	Median = 15	
-Office		20	95	<0.1 - 62	23	Median = 22	
-Laboratory		4	75	<0.1 - 102	50	Median = 48	
-Classroom		8	87.5	<0.1 - 172	65	Median = 56	
-Dormitory		15	100	11 - 441	60	Median = 15	
China	2016						Chen <i>et al.</i> , 2019
Nanjin							
-Resident homes & dormitory		50	100	3.17 - 652		Median= 85.1 Geometric mean = 76.8	

Table 26: TBPH levels in water

Location	Year(s)	n	% detect	Range (pg TBPH/L)	Mean ± SD (pg TBPH/L)	Geometric Mean / Median (pg TBPH/L)	Ref
Freshwater							
Lake Erie	2011-2012	5			10.4 ± 1.1		Venier <i>et al.</i> , 2014
Lake Huron	2011-2012	5			4.5 ± 1.1		Venier <i>et al.</i> , 2014
Lake Michigan	2011-2012	3			2.6 ± 0.2		Venier <i>et al.</i> , 2014
Lake Michigan tributary	2015						Guo <i>et al.</i> , 2017
<i>Grand River</i>		11				GM = 430	
<i>Indiana Harbor and Ship Canal</i>		11				GM = 690	
<i>Kalamazoo River</i>		12				GM = 230	
<i>Lower Fox River</i>		13				GM = 83	
<i>Saint Joseph River</i>		12				GM = 320	
Lake Ontario	2011-2012	1			0.27		Venier <i>et al.</i> , 2014

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Location	Year(s)	n	% detect	Range (pg TBPH/L)	Mean ± SD (pg TBPH/L)	Geometric Mean / Median (pg TBPH/L)	Ref
Lake Superior	2011-2012	3			3.0 ± 0.4		Venier <i>et al.</i> , 2014
Seawater							
East China sea – High Arctic	2009						Möller <i>et al.</i> , 2011b
<i>Dissolved</i>		18	25	<0.089 – 0.22	0.054* ± 0.41*	Median = 0.0445* Median = 0.0445*	
<i>Particulate</i>		14	0	<0.089	0.0445*		
East Greenland Sea	2009						Möller <i>et al.</i> , 2011a
<i>Dissolved</i>		16	25	<0.013 – 1.29	0.12* ± 0.32*	Median = 0.0065* Median = 0.0065*	
<i>Particulate</i>		16	6	<0.013 – 0.12	0.014* ± 0.03*		
Stormwater							
Norway	2020						NIVA, 2021b
Oslo							
-Bryn		-					
-Alnabru		5.2 (particles)					

*In case of values <Limit Of Quantification or <Method Detection Limit, ½ value will be used

GM = Geometric Mean

BDL = Below detection Limit

Table 27. Concentration of TBPH in sediment

Location	Year(s)	n	% detect	Range (µg TBPH/kg dw. or TOC)	Mean ± SD (µg TBPH/kg dw. or TOC)	Geometric Mean /Median (µg TBPH/kg dw. or TOC)	Ref
Freshwater							
Finland Lake Pyhäjärvi	2009	1		(dw.) <0.91			Schlabach <i>et al.</i> , 2011
China Yangtze River Delta	2011	6	100	(d.w.) 0.59 – 7.00	1.01 ± 0.38		Zhu <i>et al.</i> , 2013
Norway Lake Dalsvann	2012	3	0	(dw.) <0.01	(dw.) 0.005*	Median = 0.005*	KLIF, 2013
South African rivers Amanzimnyama Amanzimtoti Isipingo Lovu Mbokodweni Mdloti	2011	2 1 4 1 4 1		(TOC) 30 – 155 <0.6 <0.6 - 442 <0.6 <0.6	(TOC) 92.5 0.3* 113 0.3* 0.3*	(TOC) Median = 30*	La Guardia <i>et al.</i> , 2013

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Location	Year(s)	n	% detect	Range (µg TBPH/kg dw. or TOC)	Mean ± SD (µg TBPH/kg dw. or TOC)	Geometric Mean /Median (µg TBPH/kg dw. or TOC)	Ref
Mhlanga		1		<0.6	0.3*		
Mugeni		15		<0.6 - 153	4.5 ± 1.1		
Tongaat		1		<0.6	0.3*		
Umbilo		3		<0.6 - 899	327		
Umgababa		1		<0.6	0.3*		
Umhlatuzana		2		<0.6 - 54	27		
Umsimbazi		1		<0.6	0.3*		
United Kingdom	2011			(dw.)	(dw.)	(dw.)	Ganci <i>et al.</i> , 2019
River Thames		45	76	<0.02 - 14	3.5	Median = 2.1*	
USA, NC	2009			(TOC)			La Guardia <i>et al.</i> , 2012
Yadkin River							
-WWTP outfall			100	19200			
-16.8 km from outfall			100	3120			
-25.2 km from outfall			100	3570			
-44.6 km from outfall			100	2000			

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Location	Year(s)	n	% detect	Range (µg TBPH/kg dw. or TOC)	Mean ± SD (µg TBPH/kg dw. or TOC)	Geometric Mean /Median (µg TBPH/kg dw. or TOC)	Ref
Seawater							
Denmark	2009			(dw.)		(dw.)	Schlabach <i>et al.</i> , 2011
Fornæs				<0.19		Median = 0.115*	
Roskilde Marina				<0.27			
Faroe Islands						Median = 0.015*	
-Klaksvik harbour				<0.03			
-Skálafjord				<0.013			
-Tórshavn harbour				0.23			
East China Sea	2011	24	0	(dw.) <0.115	(dw.) 0.0575*	(dw.) Median = 0.0575*	Zhu <i>et al.</i> , 2013
Finland	2009			(dw.)		(dw.)	Schlabach <i>et al.</i> , 2011
Helsinki coastal bay				<0.2		Median = 0.205*	
Pori coastal bay				<0.62			

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Location	Year(s)	n	% detect	Range (µg TBPH/kg dw. or TOC)	Mean ± SD (µg TBPH/kg dw. or TOC)	Geometric Mean /Median (µg TBPH/kg dw. or TOC)	Ref
Norway Lofoten	2012	3	0	(dw.) <0.01	(dw.) 0.005*	Median = 0.005*	KLIF, 2013
Norway Åsefjorden	200			(dw.) <0.037			Schlabach <i>et al.</i> , 2011
Norway Oslofjorden	2020	1		0.11			NIVA, 2021b
South Africa Durban Bay	2011	7		(TOC) 52 - 433	(TOC) 196 ± 143	(TOC) Median = 142	La Guardia <i>et al.</i> , (2013)
Sweden Waldemarsudde Biskopsudden Torsbyfjärden				(dw.) 3.3 <1.2 <0.014		(dw.) Median = 0.6*	Schlabach <i>et al.</i> , 2011
USA San Francisco bay	2008	10	0	<0.20			Klosterhaus <i>et al.</i> , 2012

*In case of values <Limit Of Quantification or <Method Detection Limit, ½ value will be used

GM = Geometric Mean

BDL = Below detection Limit

Table 28. Concentration of TBPH in soil

Location	Year(s)	n	% detect	Range (µg TBPH/kg dw. or TOC)	Mean ± SD (µg TBPH/kg dw. or TOC)	Geometric Mean / Median (µg TBPH/kg dw. or TOC)	Ref
Norway Telemark	2012	1	0	(dw.) < 0.01			KLIF, 2013
Norway Oslo		7	0	<0.16-0.18 ng/dw			NILU, 2020

Table 29. Concentrations of TBPH in WWTP sludge

Location	Year(s)	n	% detect	Range (µg TBPH/kg dw. or TOC)	Mean ± SD (µg TBPH/kg dw. or TOC)	Geometric Mean / Median (µg TBPH/kg dw. or TOC)	Ref
Denmark Roskilde	2009	1	0	(dw.) 33			Schlabach <i>et al.</i> , 2011
Silkeborg		1	100	17			
Faroe Island (Torshavn)		2	100	6.3, 29			
Finland	2009	3	100				Schlabach <i>et</i>

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Location	Year(s)	n	% detect	Range (µg TBPH/kg dw. or TOC)	Mean ± SD (µg TBPH/kg dw. or TOC)	Geometric Mean /Median (µg TBPH/kg dw. or TOC)	Ref
Espo Helsinki Kalteva				37 42 18			<i>al.</i> , 2011
Iceland Reykjavik	2009	2	100	3.8, 15			Schlabach <i>et al.</i> , 2011
Norway Ålesund	2009	2	100	11, 11			Schlabach <i>et al.</i> , 2011
Norway Bekkelaget	2020	2		82	-	-	NIVA, 2021b
Sweden Lidingö Stockholm	2009	2	100	26 27			Schlabach <i>et al.</i> , 2011
South Africa Landfill sediments from six WWTP	2013	18		(dw.) <0.005 - 60	(dw.) 11 ± 19.6*	(dw.) Median = 0.0025*	Olunkunle <i>et al.</i> , 2015

Table 30. Concentrations of TBPH in wildlife.

Species - tissue	Location	Date	Concentration (µg TBPH/kg ww unless otherwise specified)	Remark	Reference
Invertebrates					
Asian clam (<i>Corbicula fluminea</i>)	USA	2009		Freshwater; µg/kg lipid	La Guardia <i>et al.</i> , 2012
	Yadkin river		1370		
	Outfall		816		
	16.8 km downstream		<1		
25.2 km downstream	37				
44.6 km downstream					
Bioseston/plankton	China			Freshwater; mean ± SD (range), n=6	Zheng <i>et al.</i> , 2018
	Lake Taihu	2014- 2015	0.14 ± 0.09 (<0.075 - 0.27)		
Zooplankton	Norway				NIVA, 2021a
	Lake Mjøsa	2020	<0.04	n=3	
Blue mussel (<i>Mytilus edulis</i>)	Iceland	2009	0.009	Marine; Composite sample	Schlabach <i>et al.</i> , 2011

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Species - tissue	Location	Date	Concentration (µg TBPH/kg ww unless otherwise specified)	Remark	Reference
Blue mussel (<i>Mytilus edulis</i>)	Norway	2008-2009	0.032, 0.057	Marine; n=2 (composite samples from 2 stations)	Schlabach <i>et al.</i> , 2011
Blue mussel (<i>Mytilus edulis</i>)	Norway, Lofoten, Flakstad	2012	0.005*, 0.005*, (<0.01)	Arithm. mean, median, (range), detection rate = 0% (0/3), n=3 (pooled samples of 5 individuals)	KLIF, 2013
Blue mussel (<i>Mytilus edulis</i>)	Norway, Frognerkilen River Alna Bekkelaget		0.045 0.175 0.02	Pooled soft tissues, detection rate = 100% (3/3), n=3	KLIF, 2014
Clam (<i>Lamellibranchia</i>)	China Lake Taihu	2014-2015	0.076 ± 0.099 (<0.075 - 0.25)	Freshwater; mean ± SD (range), n=6	Zheng <i>et al.</i> , 2018
Crab <i>Etisus dentatus</i>	China Xisha Islands, South Chinese	2020	0.090 ± 0.014	Marine; µg TBPH/kg lipid n=5	Hou <i>et al.</i> , 2022

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Species - tissue	Location	Date	Concentration ($\mu\text{g TBPH/kg ww}$ unless otherwise specified)	Remark	Reference
<i>Calcinus laevimanus</i> <i>Clibanarius corallinus</i>	Sea		0.065 \pm 0.008 0.069 \pm 0.014	n=6 n=4	
Earthworms (<i>Lumbricidae</i>)	Norway Oslo	2019	< 0.11	Terrestrial; n=7	NILU, 2020
Gastropod (<i>Elimia proxima</i>)	USA Yadkin river Outfall 16.8 km downstream 25.2 km downstream 44.6 km downstream	2009	 380 <1 99 36	Freshwater; $\mu\text{g TBPH/kg}$ lipid	La Guardia <i>et al.</i> , 2012
Krill (<i>Euphausiacea</i>)	Norway Oslo fjord		<0.008, <0.039, <0.045	Pooled sample, n=3	KLIF, 2014
Mud snail (<i>Bellamya purificata</i>)	China Lake Taihu	2014- 2015	0.51 \pm 0.45 (<0.075 - 1.3)	Freshwater; mean \pm SD (range), n=6	Zheng <i>et al.</i> , 2018

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Species - tissue	Location	Date	Concentration (µg TBPH/kg ww unless otherwise specified)	Remark	Reference
Opossum shrimp (<i>Mysis relicta</i>)	Norway Lake Mjøsa	2020	<0.040	Freshwater; Whole body, n=3	NIVA, 2021a
Polychaetes	Norway Oslo fjord Alna river Frognerkilen Bekkelaget		<0.037, <0.049, 0.12, <0.04 <0.02 <0.02	Pooled sample, n=6	KLIF, 2014
Prawns	Norway Oslo fjord		<0.02, <0.01, <0.015	Pooled tail soft tissues, detection rate 0% (0/3), n=3	KLIF, 2014
Red Swamp Crayfish (<i>Procambarus clarkii</i>)	China Lake Taihu	2014- 2015	<0.075	Freshwater; n=6	Zheng <i>et al.</i> , 2018
River mussels (<i>Anodonta</i>)	China Lake Taihu	2014- 2015	0.05 ± 0.04 (<0.075 - 0.044?)	Freshwater; mean ± SD (range), n=6	Zheng <i>et al.</i> , 2018
Sea cucumber	China			Marine; µg TBPH/kg lipid	Hou <i>et al.</i> , 2022

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Species - tissue	Location	Date	Concentration ($\mu\text{g TBPH/kg ww}$ unless otherwise specified)	Remark	Reference
<i>Bohadschia marmorata</i> <i>Holothuria hilla</i> <i>Thelenota ananas</i>	Xisha Islands, South Chinese Sea	2020	0.020 \pm 0.009 0.021 \pm 0.002 0.023 \pm 0.002	n=4 n=3 n=3	
Sea shells <i>Trochus sacellum</i> <i>Turbo chrysostomus</i> <i>Strombus lentiginosus</i> <i>Haliotis diversicolor</i> <i>Nerita striata</i>	China Xisha Islands, South Chinese Sea	2020	0.126 \pm 0.044 0.155 \pm 0.059 0.109 \pm 0.009 0.266 \pm 0.042 0.163 \pm 0.030	Marine; $\mu\text{g TBPH/kg lipid}$ n=5 n=6 n=3 n=5 n=3	Hou <i>et al.</i> , 2022
Fish					
Arctic char (<i>Salvelinus alpinus</i>) -liver -muscle	Denmark, Faroe Island Lake Mýranar	2008- 2009	0.2 0.011	Freshwater; n=12 (pooled sample) Muscle ($\mu\text{g/kg dw}$)	Schlabach <i>et al.</i> , 2011

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Species - tissue	Location	Date	Concentration (µg TBPH/kg ww unless otherwise specified)	Remark	Reference
Atlantic Cod (<i>Gadus morhua</i>) -liver	Norway Oslo fjord	2020	(<0.35 - <0.59) (0/15)	(range), detection rate, n=15	NIVA, 2021b
Blackeye thicklip (<i>Hemigymnus melapterus</i>)	China Xisha Islands, South Chinese Sea	2020	0.235 ± 0.109	Marine; µg TBPH/kg lipid n=3	Hou <i>et al.</i> , 2022
Blacktip grouper (<i>Epinephelus fasciatus</i>)	China Xisha Islands, South Chinese Sea	2020	0.118 ± 0.043	Marine; µg TBPH/kg lipid n=3	Hou <i>et al.</i> , 2022
Blunt-snout bream (<i>Megalobrama amblycephala</i>)	China Lake Taihu	2014- 2015	2.1 ± 0.1 (2.05 - 2.2)	Freshwater; mean ± SD (range), n=2	Zheng <i>et al.</i> , 2018
Brown trout (<i>Salmo trutta</i>) -liver	Norway, Dalsvann	2012	0.03* ± 0.02*, 0.03*, (<0.01 - 0.05)	Arithm. mean ± stdev , median, (range), detection rate = 30% (3/10), n=10	KLIF, 2013

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Species - tissue	Location	Date	Concentration (µg TBPH/kg ww unless otherwise specified)	Remark	Reference
Brown trout (<i>Salmo trutta</i>) -muscle	Norway Lake Mjøsa Lake Femunden	2020	<0.040 <0.040 (<0.040 - 0.040)	Freshwater; median, (range); detection rate Lake Mjøsa = 0% (0/10), detection rate Lake Femunden 10% (1/10)	NIVA, 2021a
Capelin (<i>Mallotus villosus</i>) -Whole body	Norway, Svalbard	2007- 2009	0.72 ± 0.29 (<0.12 - 1.31)	Marine; Lipid 2.6%, Arithm. mean ± stdev, (range), 90% detection freq., n=10	Sagerup <i>et al.</i> , 2010
Carp (<i>Carassius cuvieri</i>)	China Lake Taihu	2014- 2015	0.25 ± 0.19 (<0.075 - 0.44)	Freshwater; mean ± SD (range), n=3	Zheng <i>et al.</i> , 2018
Catfish (<i>Silurus asotus</i>)	China Lake Taihu	2014- 2015	0.71 ± 0.48 (0.39 - 1.5)	Freshwater; mean ± SD (range), n=5	Zheng <i>et al.</i> , 2018
Crucian (<i>Carassius</i>)	China			Freshwater; mean ± SD	Zheng <i>et al.</i> , 2018

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Species - tissue	Location	Date	Concentration (µg TBPH/kg ww unless otherwise specified)	Remark	Reference
<i>auratus</i>)	Lake Taihu	2014-2015	0.21 ± 0.14 (0.099 - 0.39)	(range), n=6	
Daisy parrotfish (<i>Scarus sordidus</i>)	China Xisha Islands, South Chinese Sea	2020	0.159 ± 0.032	Marine; µg TBPH/kg lipid n=4	Hou <i>et al.</i> , 2022
Dash-and-dot goatfish (<i>Parupeneus barberinus</i>)	China Xisha Islands, South Chinese Sea	2020	0.090 ± 0.014	Marine; µg TBPH/kg lipid n=6	Hou <i>et al.</i> , 2022
Doublebar goatfish (<i>Parupeneus trifasciatus</i>)	China Xisha Islands, South Chinese Sea	2020	0.090 ± 0.014	Marine; µg TBPH/kg lipid n=6	Hou <i>et al.</i> , 2022
European smelt (<i>Osmerus eperlanus</i>)	Norway Lake Mjøsa	2020	<0.040 (<0.040 - 1.68)	Freshwater; median, (range); detection rate Lake Mjøsa = 10% (1/10)	NIVA, 2021a
Flounder (<i>Platichthys flesus</i>)	Norway Oslo fjord		<0.6	Detection rate 0% (0/15), n=15	KLIF, 2014

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Species - tissue	Location	Date	Concentration ($\mu\text{g TBPH/kg ww}$ unless otherwise specified)	Remark	Reference
Honeycomb grouper (<i>Epinephelus merra</i>)	China Xisha Islands, South Chinese Sea	2020	0.083 ± 0.036	Marine; $\mu\text{g TBPH/kg lipid}$ n=3	Hou <i>et al.</i> , 2022
Indian Ocean oriental sweetlips (<i>Plectorhynchus orientalis</i>)	China Xisha Islands, South Chinese Sea	2020	0.080 ± 0.009	Marine; $\mu\text{g TBPH/kg lipid}$ n=3	Hou <i>et al.</i> , 2022
Masked spinefoot (<i>Siganus puellus</i>)	China Xisha Islands, South Chinese Sea	2020	0.127 ± 0.037	Marine; $\mu\text{g TBPH/kg lipid}$ n=3	Hou <i>et al.</i> , 2022
Peacock hind (<i>Cephalopholis argus</i>)	China Xisha Islands, South Chinese Sea	2020	0.369 ± 0.066	Marine; $\mu\text{g TBPH/kg lipid}$ n=3	Hou <i>et al.</i> , 2022
Perch (<i>Perca fluviatilis</i>) -muscle	Finland Helsinki (1 sample) Tampere (5 samples)	2009	0.002, 0.006, 0.0082, 0.0089, 0.0043	n=6 composite samples (6-10/pooled sample)	Schlabach <i>et al.</i> , 2011

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Species - tissue	Location	Date	Concentration ($\mu\text{g TBPH/kg ww}$ unless otherwise specified)	Remark	Reference
Perch (<i>Perca fluviatilis</i>) -muscle	Sweden Lake Mälaren		<0.026, 0.0051		Schlabach <i>et al.</i> , 2011
Perch (<i>Perca fluviatilis</i>) -liver	Norway, Dalsvattn	2012	0.008* \pm 0.003*, 0.008*, (<0.01 – <0.021)	Arithm. mean \pm stdev , median, (range), detection rate = 0% (0/3), n=3	KLIF, 2013
Pipefish (<i>Tylosurus crocodilus</i>)	China Lake Taihu	2014-2015	0.66 \pm 0.31 (0.38 – 1.0)	Freshwater; mean \pm SD (range); n=3	Zheng <i>et al.</i> , 2018
Polar cod (<i>Gadus morhua</i>) -whole body	Norway (arctic), Svalbard	2012	<0.01	Pooled whole fish sample, n=10	KLIF, 2013
Peppered spinefoot (<i>Siganus punctatissimus</i>)	China Xisha Islands, South Chinese Sea	2020	0.060 \pm 0.005	Marine; $\mu\text{g TBPH/kg lipid}$ n=3	Hou <i>et al.</i> , 2022
Redfin culter (<i>Cultrichthys</i>)	China	2014-		Freshwater; mean \pm SD	Zheng <i>et al.</i> , 2018

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Species - tissue	Location	Date	Concentration ($\mu\text{g TBPH/kg ww}$ unless otherwise specified)	Remark	Reference
<i>erythropterus</i>)	Lake Taihu	2015	1.8 ± 1.5 (<0.075 - 4.5)	(range), n=7	
Rice field eel (<i>Monopterus albus</i>)	China Lake Taihu	2014-2015	1.1 ± 0.77 (<0.075 - 2.5)	Freshwater; mean \pm SD (range), n=6	Zheng <i>et al.</i> , 2018
Silver fish (<i>Protosalanx hyalocranius</i>)	China Lake Taihu	2014-2015	0.078 ± 0.007 (<0.075 - 0.077)	Freshwater; mean \pm SD (range), n=6	Zheng <i>et al.</i> , 2018
Spotcheek emperor (<i>Lethrinus rubrioperculatus</i>)	China Xisha Islands, South Chinese Sea	2020	0.123 ± 0.045	Marine; $\mu\text{g TBPH/kg lipid}$ n=3	Hou <i>et al.</i> , 2022
Streamlined spinefoot (<i>Siganus argenteus</i>)	China Xisha Islands, South Chinese Sea	2020	0.127 ± 0.037	Marine; $\mu\text{g TBPH/kg lipid}$ n=3	Hou <i>et al.</i> , 2022
Sulphur goatfish (<i>Upeneus sulphureus</i>)	China Xisha Islands, South Chinese Sea	2020	0.090 ± 0.014	Marine; $\mu\text{g TBPH/kg lipid}$ n=6	Hou <i>et al.</i> , 2022
Tricolour parrotfish	China			Marine; $\mu\text{g TBPH/kg lipid}$	Hou <i>et al.</i> , 2022

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Species - tissue	Location	Date	Concentration ($\mu\text{g TBPH/kg ww}$ unless otherwise specified)	Remark	Reference
(<i>Scarus tricolor</i>)	Xisha Islands, South Chinese Sea	2020	0.190 ± 0.053	n=3	
Tripletail wrasse (<i>Cheilinus trilobatus</i>)	China Xisha Islands, South Chinese Sea	2020	0.081 ± 0.040	Marine; $\mu\text{g TBPH/kg lipid}$ n=3	Hou <i>et al.</i> , 2022
Vendace (<i>Coregonus Albula</i>)	Norway Lake Mjøsa	2020	<0.040	Freshwater; Muscle, n=10	NIVA, 2021a
Whitebait (<i>Hemisalanx prognathous</i>)	China Lake Taihu	2014- 2015	1.4 ± 1.9 (0.19 - 4.6)	Freshwater; mean \pm SD (range), n=5	Zheng <i>et al.</i> , 2018
Whitefish (<i>Alburnus</i>)	China Lake Taihu	2014- 2015	3.3 ± 5.7 (<0.075 - 14.9)	Freshwater; mean \pm SD (range), n=6	Zheng <i>et al.</i> , 2018
Whitespotted filefish (<i>Cantherhines dumerilii</i>)	China Xisha Islands, South Chinese Sea	2020	0.131 ± 0.034	Marine; $\mu\text{g TBPH/kg lipid}$ n=3	Hou <i>et al.</i> , 2022
Wolffish (<i>Anarrhichtys</i>)	China			Freshwater; mean \pm SD	Zheng <i>et al.</i> , 2018

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Species - tissue	Location	Date	Concentration ($\mu\text{g TBPH/kg ww}$ unless otherwise specified)	Remark	Reference
<i>Ocellaus</i>)	Lake Taihu	2014-2015	3.3 ± 5.7 (<0.075 - 14.9)	(range), n=3	
Yellowband parrotfish (<i>Scarus schlegeli</i>)	China Xisha Islands, South Chinese Sea	2020	0.059	Marine; $\mu\text{g TBPH/kg lipid}$ n=3	Hou <i>et al.</i> , 2022
Yellow-edged lyretail (<i>Variola louti</i>)	China Xisha Islands, South Chinese Sea	2020	0.128 ± 0.068	Marine; $\mu\text{g TBPH/kg lipid}$ n=3	Hou <i>et al.</i> , 2022
Yellow-head catfish (<i>Pelteobagrus fulvidraco</i>)	China Lake Taihu	2014-2015	1.2 ± 0.4 (0.84 - 1.9)	Freshwater; mean \pm SD (range), n=6	Zheng <i>et al.</i> , 2018
Birds					
Black-legged kittiwake (<i>Rissa tridactyla</i>) -liver	Norway, Svalbard	2007-2009	0.800 ± 0.356	Lipid 5.5%, Arithm. mean \pm stdev, 50% detection freq., n=10	Sagerup <i>et al.</i> , 2010
Black guillemot (<i>Cepphus grille</i>)	Denmark,	2008-		Skúvoy	Schlabach <i>et al.</i> , 2011

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Species - tissue	Location	Date	Concentration (µg TBPH/kg ww unless otherwise specified)	Remark	Reference
-egg	Faroe Islands Island Skúvoy Island Koltur	2009	0.021 <0.026	(pooled sample, n=9) Koltur (pooled sample, n=10)	
Black guillemot (<i>Cephus grille</i>) -egg	Denmark (arctic), East Greenland	2012	0.061 (0.020 – 0.066), 100% (3/3)	Arithmetic mean (range), detection rate, n=3	Vorkamp <i>et al.</i> , 2015
Blacktailed gull (<i>Larus crassirostris</i>) -liver	South Korea Yeonggwang, Jeollanam-do; Ulleungdo and Dokdo islands	2010-2011	2.57 (<0.75 – 9.10)	Residential predatory bird; µg TBPH/kg lipid weight; Arithm. mean (range), detection rate = 54% (for all bird species from Jin <i>et al.</i> , 2016), n=8	Jin <i>et al.</i> , 2016
Brown hawk owl (<i>Ninox scutulata</i>) -liver	South Korea Paju, Gyeonggi-do	2010-2011	20.8 (<0.75 – 80.4)	Migrant predatory bird; µg TBPH/kg lipid weight;	Jin <i>et al.</i> , 2016

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Species - tissue	Location	Date	Concentration ($\mu\text{g TBPH/kg ww}$ unless otherwise specified)	Remark	Reference
	Gunsan, Jeollabukdo			Arithm. mean (range), detection rate = 54% (for all bird species from Jin et al., 2016), n=9	
Brünnich's guillemot (<i>Uria lomvia</i>) -egg	Norway, Svalbard	2007-2009	1.8 ± 1.36 , (<0.11 - 3.4)	Lipid 11.0%, Arithm. mean \pm stdev, (range), 70% detection freq., n=10	Sagerup <i>et al.</i> , 2010
Cinereous vulture (<i>Aegypius monachus</i>) -liver	South Korea Paju, Gyeonggi-do	2010-2011	1.86 (<0.75 - 8.52)	Migrant predatory bird; $\mu\text{g TBPH/kg}$ lipid weight; Arithm. mean (range), detection rate = 54% (for all bird species from Jin et al., 2016), n=7	Jin <i>et al.</i> , 2016

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Species - tissue	Location	Date	Concentration (µg TBPH/kg ww unless otherwise specified)	Remark	Reference
Collared scops owl (<i>Otus lempiji</i>) -liver	South Korea Paju, Gyeonggi-do	2010-2011	10.8 (<0.75 – 27.8)	Residential predatory bird; µg TBPH/kg lipid weight; Arithm. mean (range), detection rate = 54% (for all bird species from Jin et al., 2016), n=6	Jin <i>et al.</i> , 2016
Common buzzard (<i>Buteo buteo</i>) -liver	South Korea Paju, Gyeonggi-do	2010-2011	12.2 (<0.75 – 63.7)	Migrant predatory bird; µg TBPH/kg lipid weight; Arithm. mean (range), detection rate = 54% (for all bird species from Jin et al., 2016), n=7	Jin <i>et al.</i> , 2016
Common eider (<i>Somateria</i>)	Norway (arctic),	2007-		Lipid 3.7%, Arithm. mean	Sagerup <i>et al.</i> , 2010

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Species - tissue	Location	Date	Concentration (µg TBPH/kg ww unless otherwise specified)	Remark	Reference
<i>mollissima</i> -liver	Svalbard	2009	1.652 ± 1.396, (<0.14 - 3.75)	± stdev, (range), 60% detection freq., n=10	
Common eider (<i>Somateria mollissima</i>) -egg	Norway, Svalbard (artic) Grinnøya, Troms	2012	0.04* ± 0.06*, 0.01*, (<0.01 - 0.21) 0.04 ± 0.02, 0.03, (0.02 - 0.08)	Arithm. mean ± stdev , median, (range), detection rate = 58% (7/12), n=12 Arithm. mean ± stdev , median, (range), detection rate = 100% (10/10), n=10	KLIF, 2013
Common kestrel (<i>Falco tinnunculus</i>) -liver	South Korea Paju, Gyeonggi-do	2010- 2011	52.1 (2.88 - 110)	Residential predatory bird; µg TBPH/kg lipid weight; Arithm. mean (range),	Jin <i>et al.</i> , 2016

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Species - tissue	Location	Date	Concentration (µg TBPH/kg ww unless otherwise specified)	Remark	Reference
				detection rate = 54% (for all bird species from Jin et al., 2016), n=4	
Double-crested cormorant (<i>Phalacrocorax auritus</i>) -egg	USA San Francisco bay	2008	<12	µg TBPH/kg lipid weight; n=3	Klosterhaus <i>et al.</i> , 2012
Eurasian eagle owl (<i>Bubo bubo</i>) -liver	South Korea Paju, Gyeonggi-do	2010-2011	170 (2.24 – 803)	Residential predatory bird; µg TBPH/kg lipid weight; Arithm. mean (range), detection rate = 54% (for all bird species from Jin et al., 2016), n=5	Jin <i>et al.</i> , 2016
Fieldfare (<i>Turdus</i>)	Norway			Pool of 2 eggs from the	NILU, 2020

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Species - tissue	Location	Date	Concentration ($\mu\text{g TBPH/kg ww}$ unless otherwise specified)	Remark	Reference
<i>pilaris</i>) -egg	Oslo	2019	<0.11	same nest; n=9	
Guillemot (<i>Uria aalge</i>) -egg	Sweden, Stora Karlsö	2009	<0.047, 0.0082	2 pooled samples (5 eggs)	Schlabach <i>et al.</i> , 2011
Glaucous gull (<i>Larus hyperboreus</i>) -plasma	Norway (arctic), Svalbard	2012	0.009* \pm 0.010*, 0.005*, (<0.01 - 0.03)	Arithm. mean \pm stdev , median, (range), detection rate = 17% (2/12), n=12	KLIF, 2013
Glaucous gull (<i>Larus hyperboreus</i>) -liver	Denmark (arctic), East Greenland	2012	0.007* (<0.14), 0% (0/4), n = 4	Arithmetic mean (range), detection rate, n	Vorkamp <i>et al.</i> , 2015
Herring gull (<i>Larus argentatus</i>) -egg	Norway, Sørøya, Finnmark	2012	0.4* \pm 1.2*, 0.005*, (<0.01 - 3.87)	Arithm. mean \pm stdev , median, (range), detection rate = 20% (2/10),	KLIF, 2013

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Species - tissue	Location	Date	Concentration (µg TBPH/kg ww unless otherwise specified)	Remark	Reference
				n=10	
Herring gull (<i>Larus argentatus</i>) -blood -egg	Norway, Oslo fjord	2012	39 ± 19 (19.6-80.3), 32.7, (15/15) <0.06, (0/15)	Arithm. mean ± stdev, median, (range), detection rate, n=15	KLIF, 2014
Herring gull (<i>Larus argentatus</i>) -blood -egg	Norway, Oslo fjord	2020	(<0.069 - <1.93) (0/15) (<0.071 - <0.08) (0/14)	(range), detection rate, n=15 (blood samples), n=14 (eggs)	NIVA, 2021b
Kittiwake (<i>Rissa tridactyla</i>) -liver	Norway (arctic), Svalbard	2007- 2009	0.8 ± 0.356, (<0.17 - 1.4)	Arithm. mean ± stdev, (range), detection rate = 50% (5/10), n=12	Sagerup <i>et al.</i> , 2010
Kittiwake (<i>Rissa tridactyla</i>) -egg	Norway (arctic), Svalbard	2012	0.09 ± 0.09, 0.05, (0.04 - 0.29)	Arithm. mean ± stdev , median, (range), detection rate = 100% (12/12),	KLIF, 2013

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Species - tissue	Location	Date	Concentration ($\mu\text{g TBPH/kg ww}$ unless otherwise specified)	Remark	Reference
				n=12	
Northern goshawk (<i>Accipiter gentilis</i>) -liver	South Korea Paju, Gyeonggi-do	2010-2011	6.5 (<0.75 – 22.4)	Migrant predatory bird; $\mu\text{g TBPH/kg}$ lipid weight; Arithm. mean (range), detection rate = 54% (for all bird species from Jin et al., 2016), n=6	Jin <i>et al.</i> , 2016
Osprey (<i>Pandion Haliaetus</i>) -eggs	USA Poplar Island Susquehanna River and Flats Anacostia and middle Potomac Rivers James River	2011-2013 2013 2011 2012	(<0.4 – 31.3), 25% (3/12), n=12 (<0.4 – 2.4), 30% (3/10), n=10 (<0.4 – 7.37), 23% (3/13), n=13 (<0.4 – 0.54), 8% (1/12), n=12	(range), detection rate, n	Lazarus <i>et al.</i> , 2016

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Species - tissue	Location	Date	Concentration (µg TBPH/kg ww unless otherwise specified)	Remark	Reference
	Back River	2013	(<0.4 – 4.3), 50% (2/4), n=4		
Oriental turtle dove (<i>Streptopelia orientalis</i>) -liver	South Korea Gyeonggi-do; Gyeongsangbuk-do; Jeollabok-do	2010-2011	<0.75	Residential herbivore bird; µg TBPH/kg lipid weight; Arithm. mean (range), detection rate = 54% (for all bird species from Jin et al., 2016), n=11	Jin <i>et al.</i> , 2016
Peregrine falcon (<i>Falco peregrinus</i>) -eggs	Canada Canadian Great Lakes – St. Lawrence River, New Brunswick	2007-2009	2.1, (<0.6 – 4.5)	µg TBPH/kg lipid weight; Arithm. mean calculated in the four eggs with concentrations above the limit of quantification (1 µg TBPH/kg lipid weight), (range), detection rate	Guerra <i>et al.</i> , 2012

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Species - tissue	Location	Date	Concentration ($\mu\text{g TBPH/kg ww}$ unless otherwise specified)	Remark	Reference
				= 33%, n=12	
Peregrine falcon (<i>Falco peregrinus</i>) -blood plasma (nestlings)	Canada Great Lakes – St. Lawrence River Rural Urban	2011- 2013	 8.0 \pm 0.2 (nd – 98.3), 40%, n=15 1.18 \pm 0.5 (nd – 9.57), 43%, n=14	$\mu\text{g TBPH/kg}$ wet weight; Arithm. mean \pm stdev (range), detection rate; n	Fernie <i>et al.</i> , 2017
Peregrine falcon (<i>Falco peregrinus</i>) -eggs	Spain Guadalajara Bilbao	2003- 2006	(<0.6 – 1.2)	$\mu\text{g TBPH/kg}$ lipid weight; (range), detection rate = 8% (1/13), n=13	Guerra <i>et al.</i> , 2012
Ring-billed gull (<i>Larus delawarensis</i>) -blood plasma -liver	Canada, Montreal St. Lawrence River	2010	Not detected (<0.04) 2.16 \pm 0.69 (<0.04 – 17.6)	Arithm. mean \pm stdev (range), detection rate = 89%; blood plasma n=30, liver n = 28	Gentes <i>et al.</i> , 2012

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Species - tissue	Location	Date	Concentration (µg TBPH/kg ww unless otherwise specified)	Remark	Reference
Sparrowhawk (<i>Accipiter nisus</i>) -egg	Norway Oslo	2019	<0.108, 0.13	Fresh eggs; n=2	NILU, 2020
Spotbilled duck (<i>Anas poecilorhyncha</i>) -liver	South Korea Paju, Gyeonggi-do	2010-2011	1.98 (<0.75 - 3.77)	Residential insectivore bird; µg TBPH/kg lipid weight; Arithm. mean (range), detection rate = 54% (for all bird species from Jin et al., 2016), n=6	Jin et al., 2016
Tawny owl (<i>Strix aluco</i>) -egg	Norway Oslo	2019	0.36*, <0.11 (<0.11 - 2.15)	Addled eggs; n=11, Arithm. mean, median (range). Detection rate = 45% (5/11)	NILU, 2020
Mammals					
Arctic fox (<i>Vulpes lagopus</i>)	Norway (arctic),			Lipid 7.1%, Arithm. mean ± stdev, 0%	Sagerup et al., 2010

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Species - tissue	Location	Date	Concentration (µg TBPH/kg ww unless otherwise specified)	Remark	Reference
-liver	Svalbard	2007-2009	Not detected	detection freq., n=10	
Brown rat (<i>Rattus norvegicus</i>) -liver	Norway Oslo	2019	(<0.12 - 2.16)	Pool of 2 individual samples for some samples; (range), detection frequency 10% (1/10), n=10	NILU, 2020
Finless porpoises (<i>Neophocaena phocaenoides</i>) -blubber	China Hong Kong	2003 - 2008	342 ± 883, (<0.04 - 3859)	µg TBPH/kg lipid weight; Arithm. mean ± stdev., (range), n=17	Lam et al., 2009
Finless porpoises (<i>Neophocaena phocaenoides</i>) -blubber	China Hong Kong	2003 - 2012	0.098 ± 0.169, (<0.02 - 1.06)	Arithm. mean ± stdev., (range), n=38	Zhu et al., 2014
Harbour Seal (<i>Phoca vitulina</i>) -liver	Norway, Terrøya, Fjellmoa,	2012	0.0145* ± 0.03*, 0.005*, (<0.01 - 0.10)	Arithm. mean ± stdev, median, (range), detection rate	KLIF, 2013

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Species - tissue	Location	Date	Concentration ($\mu\text{g TBPH/kg ww}$ unless otherwise specified)	Remark	Reference
	Beinøya, Anda			= 10% (1/10), n=9	
Harbour Seal (<i>Phoca vitulina</i>) -liver	USA, San Francisco bay	2007 - 2008	Not reported due to low recovery of standards in matrix spike tests	n=5	Klosterhaus <i>et al.</i> , 2012
Indo-Pacific humpback dolphins (<i>Sousa chinensis</i>) -blubber	China Hong Kong	2002 - 2007	0.51 ± 1.3 , (<0.04 - 5.3)	$\mu\text{g TBPH/kg}$ lipid weight; Arithm. mean \pm stdev., (range), n=17	Lam <i>et al.</i> , 2009
Indo-Pacific humpback dolphins (<i>Sousa chinensis</i>) -blubber	China Hong Kong	2003 - 2012	0.52 ± 1.5 , (<0.02 - 7.55)	Arithm. mean \pm stdev., (range), n=23	Zhu <i>et al.</i> , 2014
Moose (<i>Alces alces</i>)	Norway,			Arithm. mean \pm stdev., median,	KLIF, 2013

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Species - tissue	Location	Date	Concentration (µg TBPH/kg ww unless otherwise specified)	Remark	Reference
-liver	Seljord vest Storvald	2012	0.02* ± 0.01*, 0.02*, (<0.025 - <0.08)	(range), detection rate = 0% (0/9), n=9	
Mouse (<i>Apodemus</i> & <i>Soricidae</i>) -liver	Norway, Færstaulåi	2012	0.005*, 0.005*, (<0.01 - <0.01)	Arithm. mean, median, (range), detection rate = 0% (0/9), n=9	KLIF, 2013
Polar bear (<i>Ursus</i> <i>maritimus</i>) -plasma	Norway (arctic), Svalbard	2007- 2009	Not detected (<0.292)	Lipid 0.9%, Arithm. mean ± stdev, 0% detection freq., n=10	Sagerup <i>et al.</i> , 2010
Polar bear (<i>Ursus</i> <i>maritimus</i>) -plasma	Norway (arctic), Svalbard	2012	0.14* ± 0.16*, 0.10, (<0.018 - 0.66)	µg TBPH/L; Arithm. mean ± stdev , median, (range), detection rate = 95% (19/20), n=20	KLIF, 2013
Polar bear (<i>Ursus</i> <i>maritimus</i>)	Denmark (arctic),			Arithmetic mean (range), detection	Vorkamp <i>et al.</i> , 2015

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Species - tissue	Location	Date	Concentration ($\mu\text{g TBPH/kg ww}$ unless otherwise specified)	Remark	Reference
-adipose tissue	East Greenland	2012	0.26* (<0.128 – 0.402), 60% (3/5), n = 5	rate, n	
Red fox (<i>Vulpes vulpes</i>) -liver	Norway Oslo	2019	<0.05 - <1.40	n=10	NILU, 2020
Ringed seal (<i>Phoca hispida</i>) -liver	Norway (arctic), Svalbard	2007-2009	0.57 \pm 0.2, (<0.14 – 0.88)	Lipid 3.5%, Arithm. mean \pm stdev, (range), 60% detection freq., n=10	Sagerup <i>et al.</i> , 2010
Ringed seal (<i>Phoca hispida</i>) -plasma	Norway (arctic), Svalbard	2010	0.026* \pm 0.03*, 0.001*, (<0.01 – 0.04)	$\mu\text{g TBPH/L}$; Arithm. mean \pm stdev , median, (range), detection rate = 10% (1/10), n=10	KLIF, 2013
Ringed seal (<i>Phoca hispida</i>) -blubber	Denmark (arctic), East Greenland	2012	0.007* (<0.14), 0% (0/5), n = 5	Arithmetic mean (range), detection rate, n	Vorkamp <i>et al.</i> , 2015

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Species - tissue	Location	Date	Concentration (µg TBPH/kg ww unless otherwise specified)	Remark	Reference
	West Greenland		0.007* (<0.13), 0% (0/4), n = 4		

Table 31. Concentrations in humans of TBPH.

Location	Date	Tissue	Concentration ($\mu\text{g}/\text{kg}$ ww unless otherwise specified)	Remark	Reference
China Laizhou bay area	2011	Blood serum	260 $\mu\text{g}/\text{kg}$ lipid weight (Females, 30-39 y; n=23 (mean age 33.5 y)) < 0.25 ng/ kg lipid weight (LOD) for all other groups	Females: n = 14, 20 – 84 years (mean = 48.5 y) Males: n = 164, 20 – 84 years (mean = 45 y) Samples were pooled according to 5 age groups/ gender: 20-29, 30-39, 40-49, 50-59, >60	He <i>et al.</i> , 2013
Canada Sherbrooke region	2008 - 2009	Breast milk Maternal blood serum	(<0.15 – 6.6), 0.80, 3.0, 4.0 $\mu\text{g}/\text{kg}$ lipid weight (<7.3 – 164), 11, 33 $\mu\text{g}/\text{kg}$ lipid weight	(range), 75 P, 90 P, 95 P, detection frequency 32.4%, n=105 (range), 90 P, 95 P, detection frequency 16.7%, n=102	Zhou <i>et al.</i> , 2014
China Nanjing	2016	Fingernails	28.1/36.2, (4.21 – 689)	Median/geometric mean, (range). n = 50 Detection frequency = 100 %	Chen <i>et al.</i> , 2019

References for Annex I

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