

PBT ASSESSMENT OF SUBSTANCES – PROPOSAL FOR A TRIGGER VALUE FOR BIOACCUMULATION IN TERRESTRIAL ORGANISMS

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Introduction & objectives

In aquatic organisms trigger values for identification of bioaccumulative (“B”) and very bioaccumulative (“vB”) substances are bioconcentration factors (BCF) of >2000 and >5000, respectively. However, Annex XIII of the REACH regulation does not define similar trigger values for bioaccumulation in terrestrial organisms, despite the availability of a standardized test guideline on bioaccumulation in terrestrial oligochaetes (OECD 317). In guidance document R.11 on PBT/vPvB assessment of ECHA (2014) it is concluded that biota-soil accumulation factors (BSAF) of 0.5 and higher are indicating high bio-accumulation. The objective of the present work was to evaluate the relevant assessment criteria and to determine a proposed trigger value for bioaccumulation in terrestrial organisms based on regulatory, literature and own experimental data.

Results

- Overall BAF range found: 0.1 – 22.3 (Fig. 1)
- No clear correlation between BAF and log K_{OW} or log K_{OC}
- C_{org} -content of the test matrix influences the BAF (Fig. 2)
- Kinetic BSAF in the scope of this project: 0.21 to 14.8 (n = 35), experimental data (n = 8): 0.79 to 2.31 (Tab. 1)
- No correlation between fish BCF and earthworm BAF or BSAF (Fig. 3)
- Applying a trigger of 1.00 [basic assumption bioaccumulation = $Conc_{organism} > Conc_{medium}$] to 19 BSAF/BCF data pairs, two chemicals classified as non-accumulating in fish would be assessed as bioaccumulative in terrestrial organisms. Seven compounds would not be assumed to bioaccumulate in fish or in worms; seven substances would be considered bioaccumulative in both environments, and three chemicals would only bioaccumulate in fish but not in earthworms (Tab. 1, Fig. 3)

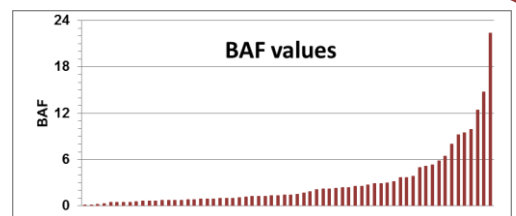


Fig. 1: BAF values for 30 substances from 64 studies.

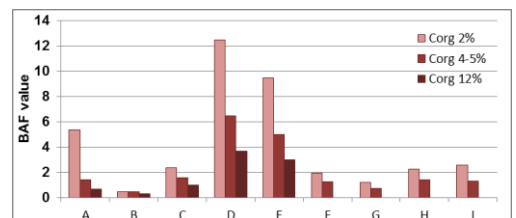


Fig. 2: C_{org} dependency of BAF for different substances (log K_{ow} 3.6 – 8.4).

Substance	log K_{OW}	log K_{OC}	This project		Calculated		Literature	
			BSAF _k 5% OM 2% C_{org}	BSAF _k 10% OM 4% C_{org}	BCF (lipid)	BCF	BCF _k	BMF
Endosulfan	4.5	6.32	1.72	2.26	$1.81 \cdot 10^5$	$9.06 \cdot 10^3$	$2.40 \cdot 10^3$	0.05
Methoxychlor	4.67	6.49	0.79	0.99	$1.24 \cdot 10^5$	$6.18 \cdot 10^3$	$1.62 \cdot 10^3$	<0
o-Terphenyl	5.5	7.23	1.61	2.00	$1.38 \cdot 10^6$	$6.92 \cdot 10^4$	$1.20 \cdot 10^4$	<1
PCB153	7.8	9.11	2.27	2.31	$1.45 \cdot 10^8$	$7.24 \cdot 10^6$	$1.85 \cdot 10^4$	3.3 - 16

Tab. 1: Experimental and literature data on BSAF, and calculated values of fish BCF and BMF according to Chapter R.11 PBT assessment, App. R.11-4.

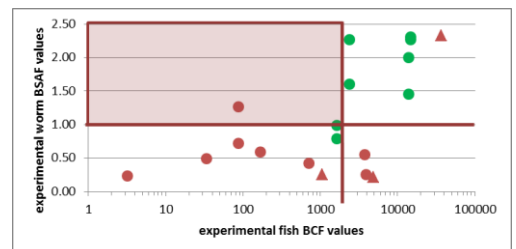


Fig. 3: Experimentally-derived worm BSAF vs. fish BCF. Total n = 19; red circles: regulatory data; green circles: this study; red triangles: literature data

Conclusion

1. Lipid- and C_{org} -normalized BSAF should be used for the assessment of terrestrial bioaccumulation.
2. No realistic estimation of an earthworm BSAF is possible on the basis of fish BCF estimates.
3. In guidance document R.11 on PBT/vPvB assessment (ECHA, 2014) it is concluded that BSAF values of 0.5 and higher are indicating high bioaccumulation. Based on the data evaluated in the present work, a BSAF trigger value of 1.00 is proposed as a general trigger to indicate bioaccumulation in terrestrial organisms in the PBT assessment framework.

PBT assessment of substances – Proposal of a trigger value for bioaccumulation in terrestrial oligochaetes

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Assessment and regulation of PBT (Persistent, Bioaccumulative and Toxic) substances, are necessary to ensure a high level of protection of human and animal health, and of the environment. In aquatic organisms, trigger values for the identification of bioaccumulative (“B”) and very bioaccumulative (“vB”) substances are bioconcentration factors (BCF) of >2000 and >5000, respectively, obtained from fish flow-through studies according to OECD 305. However, Annex XIII of the REACH regulation does not define similar trigger values for bioaccumulation in terrestrial organisms. Considering the availability of a standardized test guideline on bioaccumulation in terrestrial oligochaetes (OECD 317), the question arises whether and how the BAF and BSAF values from such earthworm bioaccumulation tests can be related to BCF criteria from fish bioconcentration tests.

In this context, the objective of the present work is the determination of a trigger for bioaccumulation in terrestrial organisms. For this aim, the study comprised the following three steps:

- 1) Literature research on available bioaccumulation factors (BAFs) both in open scientific literature and in regulatory data from several OECD 317 studies and performance of correlation analysis between soil-/substance-properties, BCF and BAF values.
- 2) Performance of bioaccumulation studies according to OECD 317 with the earthworm *Eisenia andrei* using the four model substances endosulfan, methoxychlor, o-terphenyl and PCB153.
- 3) Proposal of a trigger value for identification of bioaccumulative substances in terrestrial organisms based on the literature research and the performed experimental results.

The results clearly showed that organic carbon content of the test matrix used in the tests influences the BAF, whereas no clear correlations between log K_{ow} , log K_{oc} or similar substance properties and the BAF were observed. Additionally, no correlation was observed between substance-specific BCF from fish studies and BAF determined with earthworms. Therefore, lipid- and C_{org} -normalized BSAF should be used for the assessment of terrestrial BAF. Kinetic BSAF from both experimental studies and literature-derived values ranged from 0.21 to 14.8. Based on the data evaluated in the present work, a BSAF trigger value of 1.00 is proposed as a general trigger to indicate bioaccumulation in terrestrial organisms. Other aspects like non-depurated residues at the end of the elimination phase are discussed.