ECHA
EUROPEAN CHEMICALS AGENCY

GUIDANCE

Guidance on Information Requirements and Chemical Safety Assessment

Part C: PBT/vPvB assessment

Draft Version 3.0

February 2017

NOTE

Please note that Part C contains the concise guidance on how to assess whether or not a substance is persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB).

In-depth guidance on PBT and vPvB assessment is covered in Chapter R.11, which is currently being updated.

Hence, the content of the present draft Guidance document has not yet been modified compared to the current version available at http://echa.europa.eu/documents/10162/13643/information_requirements_part_c_en.pdf

The draft update of Part C will be modified after the written consultation of the PEG on the draft update of Chapter R.11.

Legal notice

This document aims to assist users in complying with their obligations under the REACH Regulation. However, users are reminded that the text of the REACH Regulation is the only authentic legal reference and that the information in this document does not constitute legal advice. Usage of the information remains under the sole responsibility of the user. The European Chemicals Agency does not accept any liability with regard to the use that may be made of the information contained in this document.

Guidance on Information Requirements and Chemical Safety Assessment
Part C: PBT/vPvB Assessment

Reference: XXX
Cat. Number: XXX
ISBN: XXX
DOI: XXX
Publication date: XXX 201X
Language: EN

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Preface

This document describes the information requirements under the REACH Regulation with regard to substance properties, exposure, use and risk management measures, and the chemical safety assessment. It is part of a series of guidance documents that are aimed to help all stakeholders with their preparation for fulfilling their obligations under the REACH Regulation. These documents cover detailed guidance for a range of essential REACH processes as well as for some specific scientific and/or technical methods that industry or authorities need to make use of under the REACH Regulation.

The original versions of the guidance documents were drafted and discussed within the REACH Implementation Projects (RIPs) led by the European Commission services, involving stakeholders from Member States, industry and non-governmental organisations. After acceptance by the Member States competent authorities the guidance documents had been handed over to ECHA for publication and further maintenance. Any updates of the guidance are drafted by ECHA and are then subject to a consultation procedure, involving stakeholders from Member States, industry and non-governmental organisations. For details of the consultation procedure, please see:

http://echa.europa.eu/documents/10162/13559/mb_63_2013_consultation_procedure_for_guidance_revision_2_en.pdf

The guidance documents can be obtained via the website of the European Chemicals Agency at:

http://echa.europa.eu/web/guest/guidance-documents/guidance-on-reach

Further guidance documents will be published on this website when they are finalised or updated.

This document relates to the REACH Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006[1].

[1] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p.1; corrected by OJ L 136, 29.5.2007, p.3).

1 Document History

Version	Comment	Date
Version 1	First edition	May 2008
Version 1.1	Corrigendum replacing references to DSD/DPD by CLP references (including the substitution of R-phrases by hazard statements) Editorial changes	December 2011
Version 2.0	Second edition. Full revision of this document was necessary to take into account the amendment of Annex XIII to REACH (according to Commission Regulation (EU) No 253/2011 of 15 March 2011, OJ L 69 7 16.3.2011). Main changes in the guidance document include the following: • Part C title has been changed to "PBT/vPvB assessment"; • Section C.1 has been renamed "Introduction" and subsequent Section numbering has been modified; • Description of the registrant's obligations in Section C.2 has been expanded upon to reflect those defined in the amended Section 2.1 of REACH Annex XIII. In addition, a new figure (Figure C.2-1) has been introduced to give an overview of the PBT/vPvB assessment process for the registrant; • The different steps of the PBT/vPvB assessment process, in particular the first step of comparison with the PBT and vPvB criteria, and the subsequent conclusions and consequences for the registrant have been refined to take account of the case where the registrant concludes that further information is needed but he decides not to generate additional information by considering the substance "*as if it is a PBT/vPvB*"; • Former section C.1.6 has been removed and part of its content is now in a new section (Section C.5), which has been introduced to differentiate between the case where the registrant concludes based on the available information that the substance fulfils the PBT/vPvB criteria, and the case where the registrant concludes that further information is needed but he decides not to generate additional information by considering the substance "*as if it is a PBT/vPvB*"; • The number of conclusions deriving from the first Step of the PBT/vPvB assessment process has been reduced from four to three in Section C.7 *"Conclusions on PBT or vPvB properties"*; • Minor changes to the guidance document structure and Section numbering have been implemented although the logic flow has overall been kept from the previous edition; • The document has been re-formatted to ECHA new corporate identity.	November 2014

Version 3.0	Full revision of the document to take into account the updated version of Chapter R.11 (v 3.0). Main changes in the guidance document include the following: XXX	XXX 201X

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Convention for citing the REACH regulation

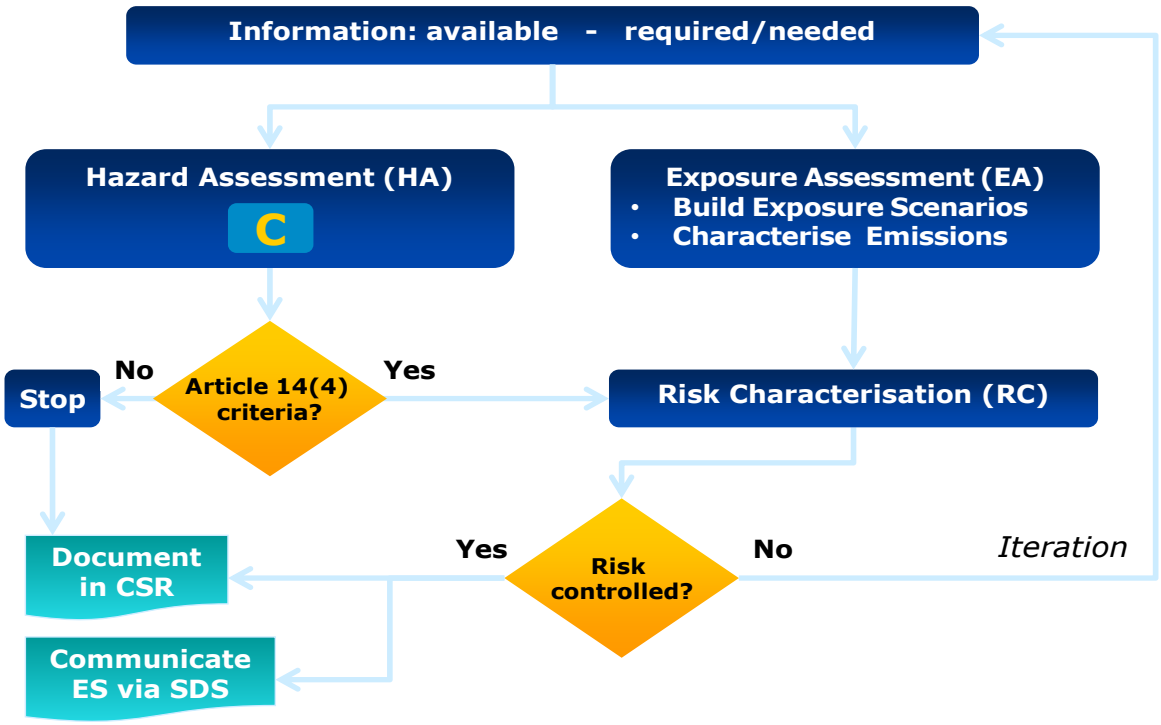
Where the REACH Regulation is cited literally, this is indicated by text in italics between quotes.

Table of Terms and Abbreviations

See Chapter R.20.

Pathfinder

The figure below indicates the scope of part C within the Guidance Document:



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C.1 Introduction

According to Section 4 of Annex I to the REACH Regulation the objective of the PBT and vPvB assessment is to determine if the substance assessed fulfils the criteria set out in Annex XIII. A conventional hazard assessment of the long-term effects and the estimation of the long-term exposure cannot be carried out with sufficient reliability for substances satisfying the PBT and vPvB criteria of Annex XIII. Therefore, a separate PBT and vPvB assessment is required.

PBT substances are substances that are persistent, bioaccumulative and toxic, while vPvB substances are characterised by a particular very high persistence in combination with a very high tendency to bio-accumulate, but not necessarily experimentally proven toxicity. These properties are defined by the criteria laid down in Section 1 of Annex XIII to REACH (the so-called "PBT and vPvB criteria").

A PBT/vPvB assessment is required for all substances for which a chemical safety assessment (CSA) must be conducted. These are in general all substances manufactured or imported in amounts of 10 or more tonnes per year that are not exempted from registration under REACH. However, some further exemptions apply, e.g. for substances present in a mixture if the concentration is less than 0.1% weight by weight (w/w) (Art. 14(2)), for on-site isolated (Art. 17) or transported intermediates (Art. 18), and for Product and Process Oriented Research and Development (Art. 9) (for further information see Section 2.2.3 of the *Guidance on Registration*).

C.2 Aim and procedure

The objective of the PBT/vPvB assessment is to determine in a stepwise procedure whether the substance fulfils the criteria given in Annex XIII to REACH and if so, to characterise the potential emissions of the substance. For a detailed description of registrant's formal duties and guidance on the assessment approach, please see *Chapter R.*11 of the *Guidance on Information Requirements and Chemical Safety Assessment (IR&CSA).*

In practice, the PBT/vPvB assessment comprises 3 steps:

1. Comparison with the criteria: The registrant has to compare the available information on intrinsic properties of the substance with the criteria for persistence, bioaccumulation and toxicity given in Annex XIII to REACH. Section 4 in *Chapter R.11* of the *Guidance on IR&CSA* provides recommendations on how to do this comparison and interpret the available information, including when the data are not directly numerically comparable with the criteria.

   If the available information does not allow to draw an unequivocal conclusion on the PBT/vPvB properties of the substance, the registrant must generate further information until an unequivocal conclusion is possible, except if the process and use conditions of the substance meet the conditions as specified in Section 3.2(b) or (c) of Annex XI to REACH and the registrant treats the substances "as if it is a PBT or vPvB".

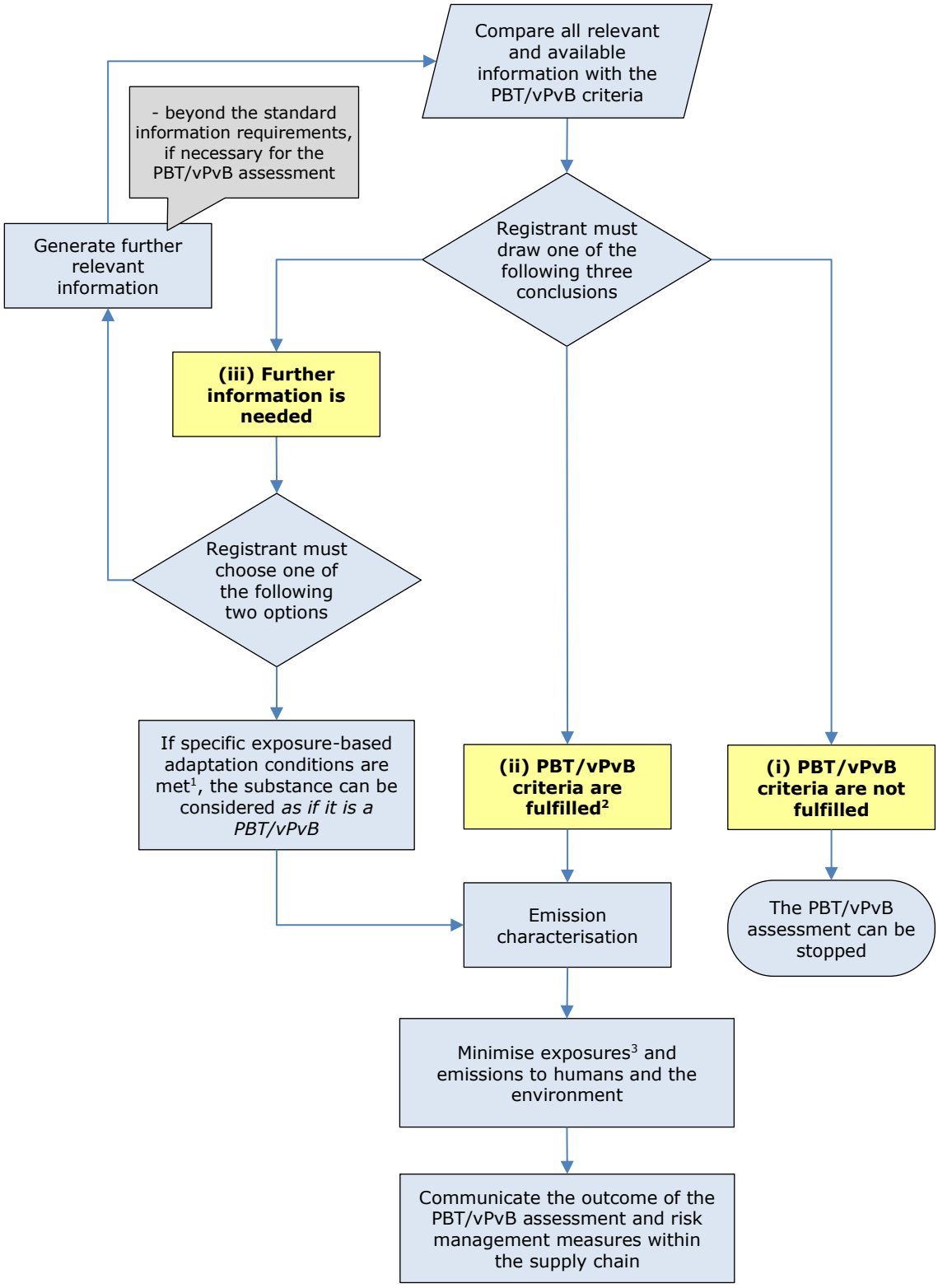
   If it is concluded that the substance is not a PBT/vPvB substance, the PBT/vPvB assessment stops after comparison with the criteria. An exposure and risk assessment as for a non-PBT/vPvB substance could however be required if the substance fulfils the criteria for any of the hazard classes or categories listed in Article 14(4) of REACH, as amended from 1 December 2010 by Article 58(1) of Regulation (EC) No 1272/2008 (CLP Regulation)[2]. These classes and categories (only) will henceforth be described as "Article 14(4) hazard classes or categories" (i.e. specifically excluding PBT or vPvB properties).

2. Emission characterisation: If a substance is confirmed to be a PBT/vPvB substance or the registrant treats the substance as if it is a PBT or vPvB, the registrant needs to estimate the amounts of the substance released to the different environmental compartments during all activities carried out by the registrant and all identified uses. In addition, it is necessary to identify the likely routes by which humans and the environment are exposed to the substance (for further guidance see Section 0 in this guidance and Section R.11.3.6 in *Chapter R.11* of the *Guidance on IR&CSA*).

3. Risk characterisation: If a substance is confirmed to be a PBT/vPvB substance or the registrant treats the substance as if it is a PBT or vPvB, the registrant must use the information obtained during the emission characterisation step for implementing on his site, and recommending to downstream users, risk management measures (RMMs) which minimise emissions and subsequent exposures of humans and the environment throughout the lifecycle of the substance that result from manufacture or identified uses.

Figure C.2-1 provides an overview of the PBT assessment process for the registrant. Step 1 is finalised when an unequivocal conclusion (i) or (ii) indicated in the figure is reached by the registrant.

[2] These are;
   a. hazard classes 2.1 to 2.4, 2.6 and 2.7, 2.8 types A and B, 2.9, 2.10, 2.12, 2.13 categories 1 and 2, 2.14 categories 1 and 2, 2.15 types A to F
   b. hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10
   c. hazard class 4.1
   d. hazard class 5.1



[1] Please refer to the conditions as specified in Section 3.2(b) or (c) of Annex XI to REACH.
[2] Normally not applicable if only screening information is available.
[3] For further information on exposure minimisation please refer to Section R.11.3.4.2 in *Chapter R.11* of the *Guidance on IR&CSA*.

Figure C.2-1: Overview of the PBT/vPvB assessment process for the registrant

C.3 PBT and vPvB criteria

Section 1 of Annex XIII to REACH sets the criteria for the identification of PBT and vPvB substances, as well as the information that must be considered for the purpose of assessing the P, B and T properties of a substance.

A substance that fulfils the criteria for persistence, bioaccumulation and toxicity described in Table C.3-1 must be considered to be a PBT substance.

A substance that fulfils the very persistent and very bioaccumulative criteria described in Table C.3-1 must be considered to be a vPvB substance.

Annex XIII to REACH allows comparison of several types of assessment information (listed under Section 3.2 of Annex XIII to REACH) against the PBT and vPvB criteria. Although not all these information types can be directly numerically compared with the criteria, this comparison must be carried out in a weight-of-evidence approach to conclude on PBT or vPvB based on expert judgement.

Table C.3-1: PBT and vPvB criteria according to Annex XIII to REACH

Property	PBT-criteria	vPvB-criteria
Persistence	A substance fulfils the persistence criterion (P) in **any** of the following situations: • $T_{1/2}$ > 60 days in marine water; • $T_{1/2}$ > 40 days in fresh- or estuarine water; • $T_{1/2}$ > 180 days in marine sediment; • $T_{1/2}$ > 120 days in fresh- or estuarine sediment; • $T_{1/2}$ > 120 days in soil.	A substance fulfils the "very persistent" criterion (vP) in **any** of the following situations: • $T_{1/2}$ > 60 days in marine, fresh- or estuarine water; • $T_{1/2}$ > 180 days in marine, fresh- or estuarine sediment; • $T_{1/2}$ > 180 days in soil.
Bioaccumulation	A substance fulfils the bioaccumulation criterion (B) when: BCF > 2000	A substance fulfils the "very bioaccumulative" criterion (vB) when: BCF > 5000
Toxicity	A substance fulfils the toxicity criterion (T) in **any** of the following situations: • NOEC or EC_{10} < 0.01 mg/L for marine or freshwater organisms; • substance is classified as carcinogenic (category 1A or 1B), germ cell mutagenic (category 1A or 1B), or toxic for reproduction (category 1A, 1B or 2); • there is other evidence of chronic toxicity, as identified by the classifications: STOT (repeated exposure), category 1 (oral, dermal, inhalation of gases/vapours, inhalation of dust/mist/fume) or category 2 (oral, dermal, inhalation of gases/vapours, inhalation of dust/mist/fume) according to the CLP Regulation.	-

C.4 Comparison with the PBT and vPvB criteria – main principles

For the identification of PBT and vPvB substances a weight-of-evidence determination using expert judgement must be applied by comparing all relevant and available information with the criteria listed in Table C.3-1 for each endpoint P, B, T, respectively. Relevant constituents, impurities and additives (generally those present in concentration ≥0.1 % w/w in the substance) as well as relevant transformation and degradation products are also

to be subjected to the PBT/vPvB assessment. None of the individual results on a specific data type can be used in isolation to draw conclusions on an endpoint.

The information used in the PBT/vPvB assessment is divided into two types: screening information[3], and assessment information.

The PBT/vPvB assessment is initiated by an evaluation of all available relevant information. Data considered under data adaptation also constitute, if relevant, part of the available information. Normally, data on ready biodegradability, octanol-water partitioning coefficient (log Kow) and environmental toxicity are available that give an indication of the P, B and T properties of a substance.

Where only screening information is available for one or more endpoints, the first step consists in screening whether the substance may fulfil the criteria, although the registrant is not able to compare the information directly numerically with the criteria (for further details, see Section C.4.1). If the technical dossier, for one or more endpoints, contains only the information as required in Annexes VII and VIII to REACH, the registrant must, based on screening information and other information available, derive either an unequivocal conclusion that the substance does not fulfil the criteria or, if this is not possible and there are indications that the substance may fulfil the criteria, further information needs to be generated to fulfil the objective of the PBT and vPvB assessment, i.e. to assess whether the substance unequivocally fulfils the criteria (for further details, see Section C.4.2).

The registrant must identify which further information is necessary. This may be either information as detailed in Annexes IX and X to REACH or other information identified by the registrant and not listed in Annexes VII to X.

This additional information must be generated regardless of the standard information requirements for the registrant's tonnage band. Generally, before generating information detailed in Annexes IX and X, a testing proposal needs to be submitted to and authorised by ECHA. The other types of information to be generated should be identified in the Chemical Safety Report (CSR).

The registrant may decide not to generate the necessary additional information if he fulfils the exposure-related conditions of Section 3.2(b) and (c) of Annex XI to REACH and by considering the substance "as if is a PBT or vPvB" with all the same consequences as for the substances which based on assessment information fulfil the PBT or vPvB criteria.

Screening and assessment of substances with high purity can sometimes be challenging. This is even more true for **substances containing multiple constituents** (UVCB-substances, well defined multi-constituent substances and mono-constituent substances with multiple impurities). For these substances, some approaches and recommendations are detailed in Section R.11.4.2.2 in *Chapter R.11* of the *Guidance on IR&CSA*.

C.4.1 Screening

If only screening information is available, it should always be considered in conjunction (i.e. P, B and T properties together) when comparing with the PBT and vPvB criteria to decide whether the substance may meet the criteria. It has to be kept in mind that the fact that a substance does not seem to meet the T criterion is not enough to stop the evaluation of the remaining endpoints in the PBT/vPvB screening step. Screening information listed in Table C.4-1 can be used as a help for comparing the screening information with screening thresholds (screening criteria) established for this purpose. This comparison should not be done in isolation, but other relevant, available information,

[3] Data listed in Annexes VII and VIII to the REACH Regulation are considered as part of screening information. Screening information can be considered in a weight-of-evidence determination to be a subset of "assessment information" as listed in Section 3.2 of Annex XIII.

including non-testing information should be assessed to analyse whether there are other indications on persistence, bioaccumulation or toxicity.

Table C.4-1: Screening information for Persistence, Bioaccumulation, and Toxicity[4, 5]

Type of screening information	Screening criterion	Conclusion
Persistence		
Biowin 2 (non-linear model prediction) and Biowin 3 (ultimate biodegradation time)	Does not biodegrade fast (probability < 0.5), and ultimate biodegradation timeframe prediction: ≥months (value < 2.25 to 2.75)	Potentially P or vP
Or	**Or**	
Biowin 6 (MITI non-linear model prediction) and Biowin 3 (ultimate biodegradation time)	Does not biodegrade fast (probability < 0.5) [a] and ultimate biodegradation timeframe prediction: ≥months (value < 2.25 to 2.75)	Potentially P or vP
Ready biodegradability test	≥ 70% biodegradation measured as DOC removal (OECD TGs 301A, 301E and 306) or ≥ 60% biodegradation measured as ThCo2 (OECD TG 301B) or ThOD (OECD TGs 301C, 301D, 301F, 306 and 310) [b]	Not P and not vP
	< 70% biodegradation measured as DOC removal (OECD TG 301A, 301E and 306) or < 60% biodegradation measured as ThCo2 (OECD TG 301B) or ThOD (OECD TGs 301C, 301D, 301F, 306 and 310)	Potentially P or vP
Modified ready biodegradability tests or enhanced screening tests [c]	Biodegradable	Not P and not vP
	Not biodegradable [c]	Potentially P or vP
Specified tests on inherent biodegradability		
• Zahn-Wellens (OECD TG 302B)	≥ 70 % mineralisation (DOC removal) within 7 d; log phase no longer than 3d; removal before degradation occurs below 15%; no pre-adapted inoculum	Not P and not vP
	Any other result	Potentially P or vP
• MITI II test (OECD TG 302C)	≥ 70% mineralisation (O2 uptake) within 14 days; log phase no longer than 3d; no pre-adapted inoculum	Not P and not vP
	Any other result	Potentially P or vP
Bioaccumulation		

[4] For further description of the tests and guidance on their interpretation see *Chapter R.11* of the *Guidance on IR&CSA*.

[5] The screening information can only be used to conclude to the direction explicitly expressed in the table. Concluding towards "not P" or "not B" using these screening information can only be done under the condition, that the registrant can justify that there are no contradicting indications from other information.

Octanol-water partitioning coefficient (experimentally determined or estimated by QSAR)	Log Kow ≤ 4.5	not B and not vB [d] (in aquatic organisms)
	Log Kow > 4.5	Potentially B or vB (in aquatic organisms)
Combination of the Octanol water partitioning coefficient with the octanol air partitioning coefficient (both experimentally determined or estimated by QSAR)	Log Kow > 2 and log Koa > 5	Potentially B (in air-breathing organisms)
Toxicity		
Short-term aquatic toxicity (algae, daphnia, fish)	EC_{50} or LC_{50} < 0.01 mg/L [e]	T criterion considered to be definitely fulfilled
Short-term aquatic toxicity (algae, daphnia, fish)	EC_{50} or LC_{50} < 0.1 mg/L [f]	Potentially T

[a] The probability is low that it biodegrades fast.

[b] These pass levels have to be reached within the 28-day period of the test. The conclusions on the P or vP properties can be based on these pass levels only (not necessarily achieved within the 10-day window) for mono-constituent substances. For multi-constituents substances and UVCBs these data have to be used with care as detailed in Section R.11.4.2.2 in *Chapter R.11* of the *Guidance on IR&CSA*.

[c] See Sections R.7.9.4 and R.7.9.5 of the *Guidance on IR&CSA, Chapter R.7b*. Expert judgement and/or use of weight-of-evidence (WoE) also employing other information may be required to reach a conclusion (i.e. concerning "biodegradable/ not biodegradable") also because some of the current guidance in the Chapter on degradability is not so prescriptive.

[d] Care must be taken and a case-by-case assessment made in case a substance is known to bioaccumulate by a mechanism other than passive diffusion driven by hydrophobicity. *E.g.* specific binding to proteins instead of lipids might result in an erroneously low bioaccumulation potential if it is estimated from log Kow.

Care must also be taken for substances classified as polar non-volatiles (with low log Kow and high log Koa). This group of substances has a low bioaccumulation potential in aquatic organisms but a high bioaccumulation potential in air-breathing organisms (unless they are rapidly metabolised).

[e] These threshold values only apply for the aquatic compartment.

[f] These threshold values only apply for the aquatic compartment.

C.4.2 Assessment

If, on the basis of the screening assessment, the registrant cannot draw an unequivocal conclusion on whether the criteria for P, B and T or for vP and vB are met or not, the registrant may choose to treat the substance "as if it is a PBT or vPvB" substance (see Section 0). If the registrant decides to further evaluate the properties of a substance that, based on the screening assessment, potentially fulfils the PBT or vPvB criteria, a definitive assessment of P/vP including assessment of any newly generated additional information should be conducted first. Definitive assessment of P/vP should normally be based on degradation half-life data collected under adequate conditions for the relevant compartment(s) of exposure (see Section C.4.2.1).

If the substance is considered to fulfil the P and/or vP criterion, the PBT/vPvB assessment is continued by evaluation of the B/vB criterion including assessment of any newly generated additional information. Definitive assessment of B/vB should normally be based on measured data on bioconcentration in aquatic species (see Section C.4.2.2).

If the substance is not identified as vPvB but considered to fulfil the P and B criteria, the PBT assessment is continued by evaluation of the T criterion. Definitive assessment of T should be based on evaluation of the data for classification of the substance for human health hazards and/or on no-observed effect concentration(s) (NOECs) or EC_{10} from long-term toxicity tests with aquatic organisms (see Section C.4.2.3).

However, for substances for which persistence testing is difficult or practically impossible, like e.g. for certain multi-constituent or very poorly water soluble substances, it may be more reasonable to start the PBT/vPvB assessment by evaluating the B criterion (for further guidance see Section R.11.4.2 in *Chapter R.11* of the *Guidance on IR&CSA*).

The registrant must continue the cycle of generation of relevant additional data/information and assessment until he is able to draw an unequivocal conclusion – i.e. either that the substance does not fulfil the PBT and vPvB criteria or that it fulfils the PBT or the vPvB criteria.

C.4.2.1 Persistence

The detailed testing strategy on degradation for PBT/vPvB assessment is set out in Section R.11.4.1.1 and Figure R.11-3 in *Chapter R.11* of the *Guidance on IR&CSA*. It is based on a weight of evidence approach starting with the review of all available screening test data and non-test data (e.g. (Q)SAR model predictions, read-across, and chemical categorisation). The threshold values for the screening methods are given in Table C.4-1. For example, in some cases, the performance of a screening biodegradation test may deliver sufficient information to draw the conclusion that the substance can be considered as "not P".

If persistence of a substance cannot be excluded based on available data or further generation of screening information, there is need to carry out (a) degradation simulation test(s). If simulation testing in water is feasible, this should normally be preferred as the first test, unless there is a specific reason to start with a test in soil or the sediment compartment. When degradation simulation test data are available for one compartment, it needs to be considered whether these results together with the other available data are sufficient to draw a conclusion also for the other two compartments or whether further simulation testing is necessary. The persistence assessment needs to be concluded for all three (five) compartments, ie. (marine) water, (marine) sediment and soil.

C.4.2.2 Bioaccumulation

A detailed test strategy for bioaccumulation testing for PBT/vPvB assessment is set out in Section R.11.4.1.2 and Figure R.11-4 in *Chapter R.11* of the *Guidance on IR&CSA*. In general, all existing information on the bioaccumulation potential of a substance should be collected and evaluated first before a decision on the necessity to conduct further testing is drawn. The existing data may include laboratory bioconcentration tests (aquatic, terrestrial and benthic) and field studies on biomagnification or bioaccumulation. Such available information might be sufficient to conclude whether the substance is vB, B, or not B (see Section R.11.4.1.2 in *Chapter R.11* of the *Guidance on IR&CSA*).

If the substance has a log Kow ≤ 4.5, no specific uptake mechanism apart from hydrophobicity/lipophilicity is known and the possibility for accumulation in other food chains than the aquatic food chain can be ruled out (log Koa < 2 and log Kow < 5) , then the substance can be considered as not B and not vB and further evaluation of the B and vB criteria is not necessary.

In other cases, where:

- no direct data on bioaccumulation (e.g. BCF, BAF or BMF data) are available and the substance has a log Kow > 4.5, or the partitioning process into aquatic organisms is not driven by hydrophobicity/lipophilicity;
- there are other indications that the substance might bioaccumulate;
- direct data on bioconcentration are available but these data are not reliable and/or consistent to a degree sufficient to conclude whether the B or vB criteria are met (for all substances subject to PBT/vPvB assessment);

the B and vB properties should be evaluated in more detail and, if necessary, further information must be generated.

In this further evaluation, non-testing data should be used as indicators for limited bioaccumulation in a weight-of-evidence assessment together with supplementary information to examine whether the substance potentially meets the B and vB criteria. Because the indicators for limited bioaccumulation (e.g. molecular weight and size of the molecule, octanol solubility or log Kow) are on their own considered to be insufficient to abstain from confirmatory testing, the availability of other reliable information indicating a low bioaccumulation potential is essential. This supplementary information may comprise

data showing no toxicity in a chronic toxicity study with mammals, no uptake in a toxicokinetic study, or it could be a bioconcentration study with invertebratesEvidence of significant uptake of a substance in fish or mammals after prolonged exposure is a contraindication to using the above indicators of limited bioconcentration.

If further testing is necessary, fish flow-through test, if feasible, is the preferred test. Only if not feasible, fish dietary bioaccumulation test should be considered. In a PBT/vPvB assessment under REACH, the greatest weight is given to valid and plausible BCF-test data: this is based on current understanding that BCF is the most representative parameter to reflect the bioaccumulation potential of substances for which aquatic bioaccumulation is relevant. In case BCF values are inconsistent with other data types, it is very important to carefully analyse the reasons for such inconsistence and discuss the plausibility of the BCF values in this context. Conclusion on B/vB-assessment needs to be based on consideration of all data types together.

C.4.2.3 Toxicity

A strategy for toxicity assessment and testing in the context of the PBT/vPvB assessment…is set out in Section R.11.4.1.3 and Figure R.11-5 in *Chapter R.11* of the *Guidance on IR&CSA*. The strategy starts with the evaluation of the classification of the substance according to Regulation EC No 1272/2008. If any classification criterion leading to the assignment of the hazard statements H350, H340, H372, H373 H350i, H360 and H361[6] is met, the substance fulfils the T criterion[7] and there is no need to perform any further aquatic studies for T assessment.

When no such classification is assigned, data on aquatic toxicity should be evaluated. When no chronic toxicity data are available, a substance is considered to meet the T-criterion when an acute L(E)C_{50} value from a standard toxicity (or reliable non-standard) test is <0.01 mg/l. When the L(E)C_{50} is <0.1 mg/l, the substance is considered to meet potentially the T-criterion, and consequently the substance is referred to definitive T testing and chronic studies are required (regardless of the tonnage band). Note however that, due to animal welfare concerns, the general scheme of testing and confirming first P and B should be applied before further T-testing is considered. Also, vertebrate-animal testing should be minimised by first testing non-vertebrate species. Normally, the testing order for conclusion on T based on chronic data is *Daphnia* and then fish[8], unless there is evidence that fish are more sensitive than *Daphnia*. If the T-criterion is fulfilled by the chronic algae or *Daphnia* data, a chronic fish test is not necessary. If however a long term test on *Daphnia* or algae provides a NOEC or EC_{10} close to but above 0.01 mg/l, a long-term fish study is likely to be needed to confirm "not T".

For certain hydrophobic/lipophilic substances (with a log Kow >5) acute toxicity may not occur at the limit of the water solubility of the substance tested (or the highest concentration tested). In such situations, chronic toxicity with a NOEC/EC_{10} <0.01 mg/l cannot be excluded even if available short-term toxicity data indicate L(E)C_{50} values >0.1 mg/l, because these substances may not have had sufficient time in the acute test to be significantly taken up by the test organisms and to reach equilibrium partitioning (see Section R.11.4.3 Integrated testing strategy for T testing, Figure R.11-5 and decision tree Steps 2, 5 and 6 in *Chapter R.11* of the *Guidance on IR&CSA*).

In the absence of definitive information on T, for substances with very high hydrophobicity/lipophilicity, a weight-of-evidence or group approach for long-term toxicity

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[6] H360 and H361 here include also all the possible combinations (e.g. H360F, H360FD, etc).

[7] Note the obligation to check whether the criteria for assigning a respective classification are fulfilled. It is not enough to check whether any of the mentioned hazard statements has already been assigned to the substance.

[8] Algae are not mentioned here because chronic algae data (i.e. 72h NOEC) normally will be available, as it can be easily obtained from the same 72h standard test from which the acute endpoint (72h EC_{50}) is derived.

may be used to predict whether long-term effects are likely to occur. If convincing evidence is available that aquatic toxicity is not expected to occur at <0.01 mg/l, chronic testing may not be required. Such evidence could comprise reliable QSAR predictions, read-across or grouping approaches indicating narcotic mode of action together with measured low chronic fish toxicity data from a related compound. Supporting information could be chronic data on aquatic species such as, e.g., daphnids, algae or sediment dwelling species and/or low acute or chronic mammalian and avian toxicity. Any conclusions on the suitability of data and the T criterion should be based on expert judgement and weight-of-evidence. If data from this approach provide insufficient evidence that toxicity will not occur in a chronic test long-term T testing must be carried out in case the P and B criteria are already considered to be met.

C.5 Conclusions on PBT or vPvB properties

A detailed scientific analysis of the persistence, bioaccumulation and toxicity should be brought together into a clear overall conclusion. Three conclusions for the comparison of the information on the PBT properties with the criteria are possible (for further guidance see Section R.11.4.4 in *Chapter R.11* of the *Guidance on IR&CSA*).

i. The substance does not fulfil the PBT and vPvB criteria. The available information show that the properties of the substance do not meet the specific criteria provided in REACH Annex XIII Section 1, or if the information does not allow a direct comparison with all the criteria there is no indication of P or B properties based on screening information or other information.

   In this case, the PBT/vPvB assessment stops at this point. An exposure assessment and risk characterisation as for a non-PBT/vPvB substance may however be required if the substance fulfils the criteria for classification according to the CLP Regulation, in any of the Article 14(4) hazard classes or categories[9] (see Section C.2).

ii. The substance fulfils the PBT or vPvB criteria. The available information show that the properties of the substance meet the specific criteria detailed in REACH Annex XIII Section 1 based on a weight-of-evidence determination using expert judgement comparing all relevant and available information listed in Section 3.2 of Annex XIII to REACH with the criteria.

   In this case an emission and risk characterisation for PBT/vPvB substances in accordance with the stipulations of Annex I to REACH is required and a SDS needs to be generated (or any existing SDS updated).

iii. The available data information does not allow to conclude (i) or (ii). The substance may have PBT or vPvB properties. Further information for the PBT/vPvB assessment is needed.

   In this case a registrant has two options:

   - He generates the required information (depending on the information needed, the submission of a testing proposal may be required) and concludes on the PBT/vPvB properties of the substance concerned once the necessary data are available (i.e. conclusion (i) or (ii)); or
   - He refrains from generating further information and treats his substance "as if it is a PBT or vPvB". This is only allowed if the registrant applies specific exposure-based adaptation conditions (Section 3.2(b) or (c) of Annex XI to REACH). In this case, the same further obligations apply as if the conclusion (ii) had been drawn.

[9] Please note that PBT/vPvB properties are excluded.

C.6 Further actions if a substance is identified as a PBT or a vPvB or considered by the registrant "as if it is a PBT or vPvB"[10]

If it is concluded that the substance is a PBT or vPvB substance, or that the registrant considers the substance "as if it is a PBT or vPvB", the registrant must clearly indicate in the registration dossier, CSR and SDS which of the two cases applies to his substance, and must conduct an emission characterisation and a risk characterisation in accordance with Article 14 (4).

If ECHA's Member State Committee (MSC) concludes that the substance is identified as a substance of very high concern (SVHC) due to its PBT or vPvB properties the registrant must update his registration dossier, CSR and SDS accordingly. He must also carry out an emission characterisation and a risk characterisation as mentioned above. Generally, if a substance contains one or more constituents, impurities and/or additives with *PBT/vPvB properties* in individual amounts ≥ 0.1 % (w/w) or if transformation/degradation products with the *PBT/vPvB properties* in relevant amounts are being generated, the substance must be considered as PBT/vPvB and hence subjected to emission characterisation and risk characterisation. For discussion on what are "relevant" constituents, impurities, additives and transformation/degradation products, please, see *Sections R.11.3.2.1 and R.11.4.1* in *Chapter R.11* of the *Guidance on IR&CSA*.

The main objective of the emission characterisation is to estimate the amounts (and rates) of the *PBT/vPvB substance* released to the different environmental compartments and to identify the likely routes by which humans and the environment are exposed to the substance. A registrant has only to take care of his own tonnage[11]. In co-operation with his downstream users he has to cover, where relevant, any manufacture in the EU he is responsible for, his own uses and all identified uses including all resulting lifecycle stages.

The principal tool to achieve this objective is exposure scenarios (ES(s)). Part D and *Chapters R.12 to R.18* of the *Guidance on IR&CSA* provide guidance on how to develop ESs for substances in general. Parts of the exposure assessment guidance are relevant also for *PBT/vPvB substances* (i.e. emission estimation and assessment of chemical fate and pathways). However, since the objectives are not the same the general scheme for exposure assessment needs to be adapted to the requirements of emission characterisation for *PBT/vPvB substances*. Guidance is given below on some issues where special considerations are needed for *PBT/vPvB substances*. In the context of the emission characterisation, the registrant needs to develop ES(s) for all identified uses of his *PBT/vPvB substance*, unless he concludes to advise in his technical dossier (and SDS) against certain uses of his substance. In this latter case he does not need to perform an emission characterisation or other risk management work related to these uses.

As *PBTs and vPvBs* are substances of very high concern, the registrant must pay special attention to the level of detail of his assessment and whether its accuracy and reliability is sufficient for a *PBT/vPvB substance*. Where generic scenarios and assumptions may be sufficient for exposure assessment of non PBT/vPvB-substances, specific scenarios and data will most likely be needed throughout an emission characterisation for *PBT/vPvB-substances*. All effort necessary should be made to acquire for manufacture and any identified use throughout the lifecycle, site- and product-specific information on emissions and likely routes by which humans and the environment are exposed to the substance. The emission characterisation must in particular be specific in the use description and concerning RMMs, and must furthermore contain an estimation of the release rate (e.g.

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[10] For the purpose of this section, when reference to a "*PBT or vPvB substance*(s)" in italics is made, this covers both the case that the substance has been concluded to fulfil the PBT/vPvB criteria and the case that the registrant considers the substance "as if it is a PBT/vPvB".

[11] However, it can be useful to consider on a voluntary basis exposure resulting from emissions of the same substance manufactured or imported by other registrants (i.e. the overall estimated market volume). See Part A.2.1 of the *Guidance on IR&CSA*.

kg/year) to the different environmental compartments during all activities carried out during manufacture or identified uses, or waste disposal (for further guidance see Section R.11.3.6.1 in *Chapter R.11* of the *Guidance on IR&CSA*).

The objective of a risk characterisation for *PBT/vPvB substances* is to use the information obtained in the emission characterisation step to implement on a registrant's site and to recommend to his downstream users RMMs which minimise exposures and emissions to humans and the environment throughout the lifecycle of the substance that results from manufacture or identified uses (Section 6.5 of Annex I to REACH). To this end, the minimisation of exposures and emissions to humans and the environment needs to be considered throughout the development of ES(s). The need or a potential to (further) minimise emissions or exposure may therefore be recognised at any point in the development of an ES. In this way, the appropriateness and effectiveness of RMMs and Operational Conditions (OCs) should be assessed in the development of the ES. Furthermore, for a substance considered by the registrant "*as if it is a PBT or vPvB*", the ES must be in line with the fact that the adaptation criteria of Section 3.2(b) and/or (c) of Annex XI to REACH are fulfilled.

Suitable options and measures to minimise emissions of and exposure[12] to a *PBT/vPvB substance* are, for instance, substitution of the substance or reduction of its use when technically possible, manufacture and use only under strictly controlled conditions and handling of the substance by trained personnel only (for further guidance see Section R.11.3.6.2 in *Chapter R.11* of the *Guidance on IR&CSA*).

The final ES, or ES(s) in case of different uses, must be presented under the relevant heading of the CSR, and included in an annex to the SDS. It must describe the required OCs and RMMs in a way that downstream users can check whether they have to implement any measures in order to minimise emissions or exposures of humans and the environment.

[12] For further information on exposure minimisation please refer to Section R.11.3.4.2 in *Chapter R.11* of the *Guidance on IR&CSA*.

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