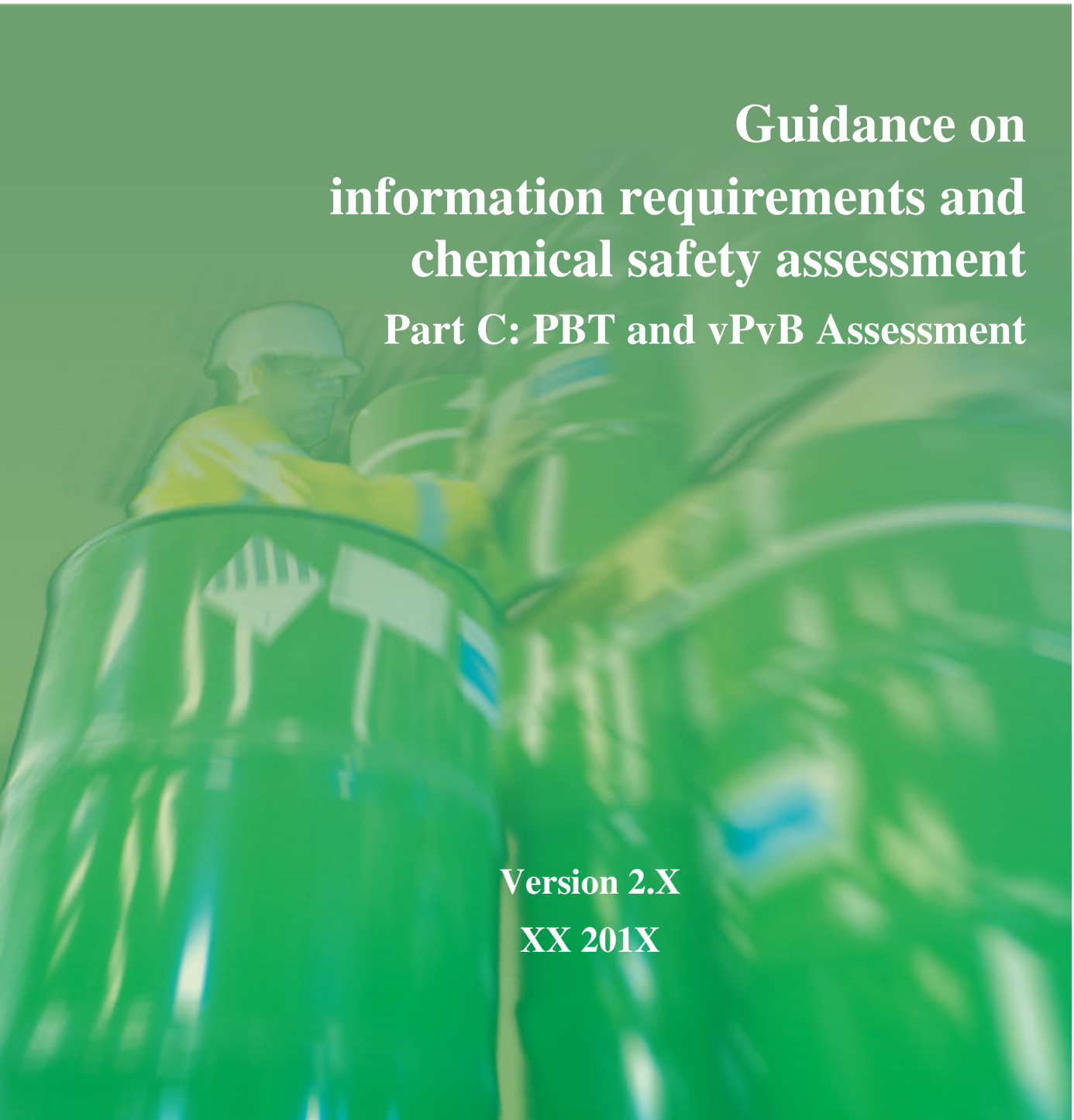
1
2
3
4



# Guidance on information requirements and chemical safety assessment

## Part C: PBT and vPvB Assessment

**Version 2.X**

**XX 201X**

LEGAL NOTICE

This document contains guidance on REACH explaining the REACH obligations and how to fulfil them. 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. The European Chemicals Agency does not accept any liability with regard to the contents of this document.

***Guidance on information requirements and chemical safety assessment***
***Part C: PBT and vPvB Assessment***

**Reference:** XX
**Publ.date:** XX
**Language:** EN



If you have questions or comments in relation to this document please send them (indicating the document reference, issue date, chapter and/or page of the document which your comment refers to) using the Guidance feedback form. The feedback form can be accessed via the ECHA Guidance website or directly via the following link:
https://comments.echa.europa.eu/Comments/FeedbackGuidance.aspx

**European Chemicals Agency**
Mailing address: P.O. Box 400, FI-00121 Helsinki, Finland
Visiting address: Annankatu 18, Helsinki, Finland

# PREFACE

This document describes the information requirements under REACH 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 REACH. 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 REACH.

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/10162/17203/mb_14_2011_consultation_procedure_guidance_en.pdf

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

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, corrected version in OJ L136, 29.5.2007, p.3); amended by: Council Regulation (EC) No 1354/2007 of 15 November 2007 adapting Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), by reason of the accession of Bulgaria and Romania, Commission Regulation (EC) No 987/2008 of 8 October 2008 as regards Annexes IV and V; Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures; Commission regulation No 453/2010 of 20 May 2010 as regards Annex II; Commission Regulation No 252/2011 of 15 March 2011 as regards Annex I; Commission Regulation No 253/2011 of 15 March 2011 as regards Annex XIII; Commission Regulation No 366/2011 of 14 April as regards Annex XVII (Acrylamide), Commission Regulation No 494/2011 of 20 May 2011, as regards Annex XVII (Cadmium).

**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)<br><br>Editorial changes | December 2011 |
| Version 2.X | XX | XX |

## Part C: PBT and vPvB assessment

### Convention for citing the REACH regulation

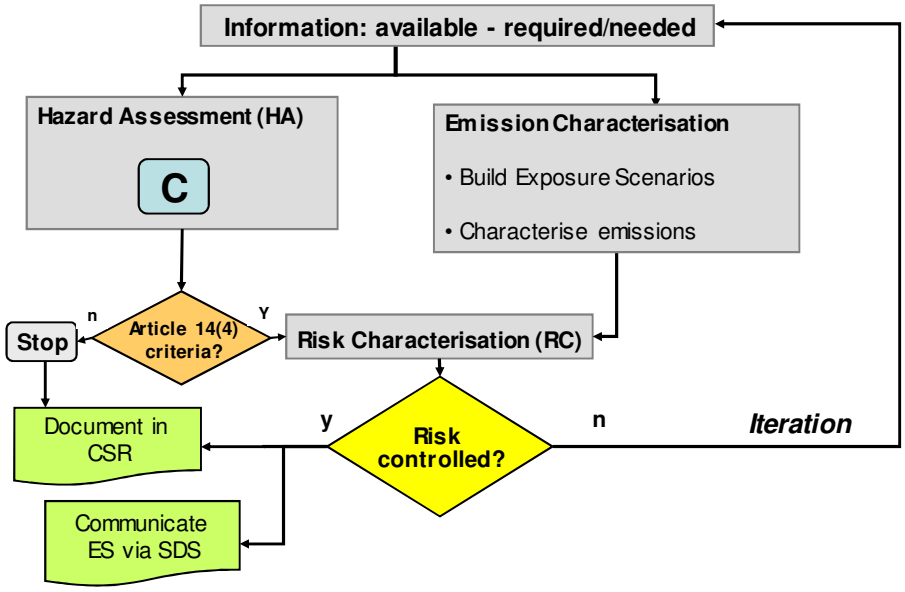
Where the REACH Regulation is cited literally, this is indicated by text in italics between quotes.

### Table of Terms and Abbreviations

See Chapter R.20

### Pathfinder

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



# TABLE OF CONTENTS



## TABLES



## FIGURE

# C.1 PBT AND vPvB ASSESSMENT

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) (see *Guidance on Registration*, Section 2.2.3, for further information).

## C.1.1 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. 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

   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, 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 (see Sections C.1.4 and R.11.3.6 for further guidance).

---

[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

3. Risk characterisation: 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 results from manufacture or identified uses.

Figure C1-1 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.

## Part C: PBT and vPvB assessment

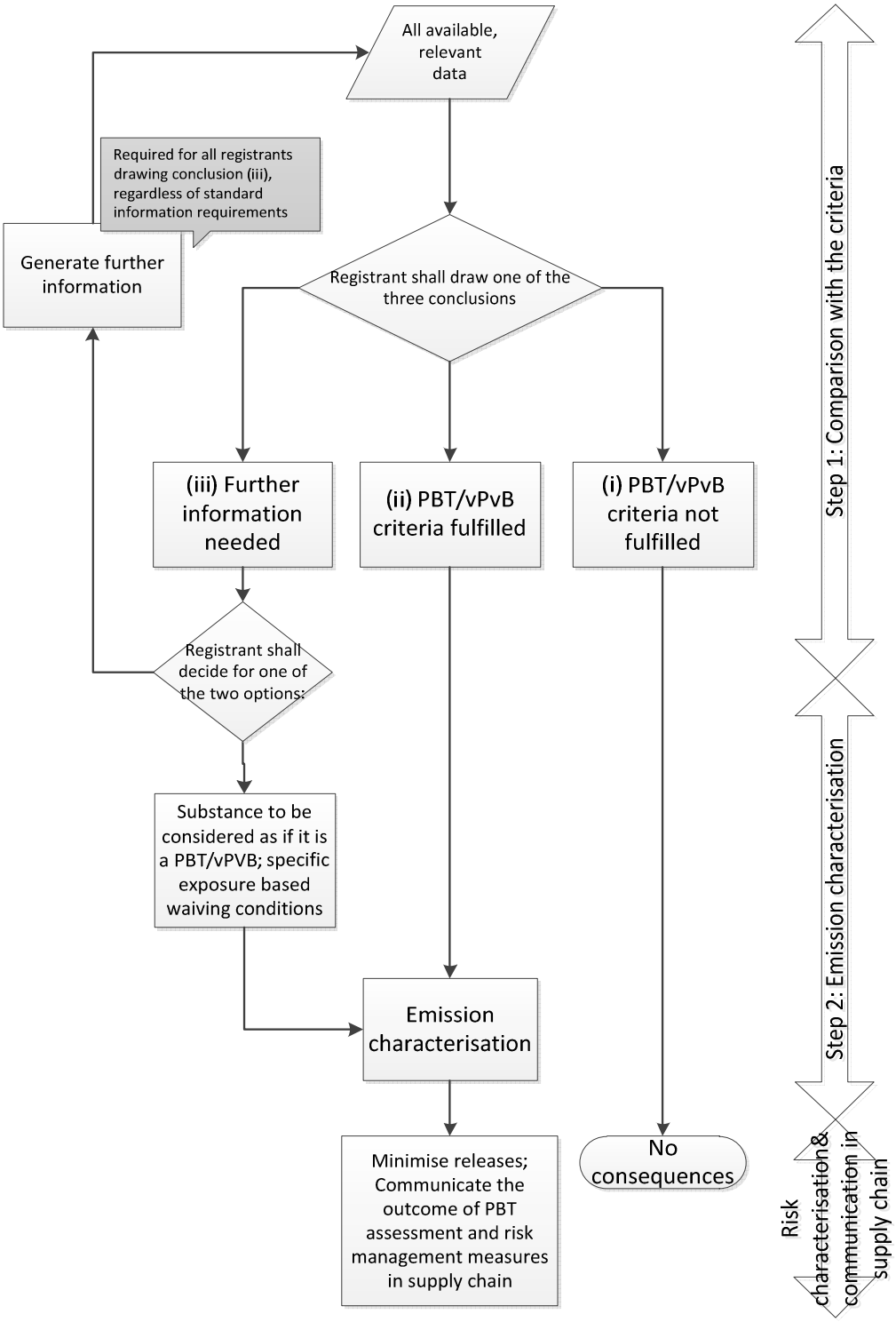



**Figure C1-1:** Overview of the PBT/vPvB assessment process for the registrant

## C.1.2 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 C1-1 must be considered to be a PBT substance.

A substance that fulfils the very persistent and very bioaccumulative criteria described in Table C1-1 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 compared with the criteria, this comparison must be used in a weight-of-evidence approach to conclude on PBT or vPvB based on expert judgement. It should however be noted that, even where a criterion is marginally not fulfilled, the overall evidence can be sufficient to justify the conclusion that a substance fulfils the Annex XIII criteria. This includes for example substances that do not fulfil the persistence criteria but bioaccumulate significantly and are measured in increasing levels over time in biota distant from anthropogenic sources (see Section R.11.4.1.4 for further guidance).

**Table C1-1**: 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:<br>- $T_{1/2}$ > 60 days in marine water, or<br>- $T_{1/2}$ > 40 days in fresh- or estuarine water, or<br>- $T_{1/2}$ > 180 days in marine sediment, or<br>- $T_{1/2}$ > 120 days in fresh- or estuarine sediment, or<br>- $T_{1/2}$ > 120 days in soil. | A substance fulfils the "very persistent" criterion (vP) in any of the following situations:<br>- $T_{1/2}$ > 60 days in marine, fresh- or estuarine water, or<br>- $T_{1/2}$ > 180 days in marine, fresh- or estuarine sediment, or<br>- $T_{1/2}$ > 180 days in soil. |
| **Bioaccumulation** | A substance fulfils the bioaccumulation criterion (B) when:<br>BCF > 2000 | A substance fulfils the "very bioaccumulative" criterion (vB) when:<br>BCF > 5000 |
| **Toxicity** | A substance fulfils the toxicity criterion (T) in any of the following situations:<br>- NOEC or EC10 < 0.01 mg/L for marine or freshwater organisms, or<br>- 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), or<br>- 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.1.3 Comparison with the PBT and vPvB criteria

The PBT and vPvB assessment of a substance must be based on a comparison of all the relevant information available with the criteria. 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. 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 C1-1. In particular, such judgment is needed where the available information cannot be directly compared with the criteria. This information is divided into two types: screening information, and assessment information, whereas screening information (corresponding to REACH Annex VII and VIII information) can be considered as a subset of assessment information.

The PBT and vPvB assessment of a substance must be based on all the relevant information available, which is normally for the registrant the information that must be submitted as part of the technical dossier as listed in Annexes VII and VIII to REACH, including the physicochemical, hazard and exposure information generated in the context of the CSA. 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 with the criteria. 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, consider whether 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.

It is the task of the registrant to assess if the information that is available and/or produced is sufficient to conclude whether the substance is a PBT or a vPvB substance or not. If such an unequivocal conclusion cannot be drawn, further 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 must be generated by the registrant to allow judgement as to whether the substance fulfils the Annex XIII criteria.

This additional information must be generated regardless of the standard information requirements of the registrant based on his tonnage band. Furthermore, if the PBT/vPvB assessment identifies that further information is needed, Column 2 waivers of REACH Annexes VII to X cannot be applied. 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).

**Commentaire [JPT1] :** Subject of check still.

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.

The PBT assessment is initiated by an evaluation of all available information. Normally, data on ready biodegradability, octanol-water partitioning coefficient (log Kow) and environmental toxicity are available that give an indication on the P, B and T properties of a substance.

Table C1-2 gives an overview of the screening criteria that can be used for a screening assessment to decide whether additional information on the PBT or vPvB properties must be generated.

When the screening criteria and other information available to the registrant including non-testing information do not clearly indicate that there is no concern that the substance could

meet the Annex XIII criteria (Table C1-1), a stepwise approach is followed for the definitive assessment of the P, B and T criteria, which is further outlined below.

Screening assessment

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 has to be regarded as a potential PBT or vPvB. 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. Similarly, conflicting evidence arising from further information, e.g. monitoring data indicating potential P or B properties, needs to be considered in the assessment and in the overall conclusion on the PBT or vPvB properties (see Section R.11.4.1.4 for further guidance). Screening criteria listed in Table C.1-2 can be used as a help for comparing the screening information with the criteria. This should not be done in isolation, but other information, including non-testing information should be assessed to analyse whether there are other indications on persistence, bioaccumulation or toxicity.

## Part C: PBT and vPvB assessment

1 **Table C1-2**: Screening criteria for Persistence, Bioaccumulation, and Toxicity [3, 4]

| Type of screening information | Criterion | Conclusion |
|---|---|---|
| **Persistence** | | |
| Ready biodegradability test | Readily biodegradable | Not P and not vP |
| | Not readily biodegradable | Potentially P or vP |
| Enhanced ready biodegradability test | Readily biodegradable | Not P and not vP |
| | Not readily biodegradable | Potentially P or vP |
| Specified tests on inherent biodegradability | | |
| - Zahn-Wellens (OECD 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 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 |
| 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 < 2.2) | 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) and ultimate biodegradation timeframe prediction: ≥months (value < 2.2) | Potentially P or vP |
| **Bioaccumulation** | | |
| | | |
| Octanol-water partitioning coefficient (experimentally determined or estimated by QSAR) | Log Kow ≤ 4.5 | not B and not vB |
| | Log Kow > 4.5 | Potentially B or vB |
| **Toxicity** | | |
| Short-term aquatic toxicity (algae, daphnia, fish) | EC50 or LC50 < 0.01 mg/L | T, criterion considered to be definitely fulfilled |
| Short-term aquatic toxicity (algae, daphnia, fish) | EC50 or LC50 < 0.1 mg/L | Potentially T |
| | | |

**Commentaire [JPT2] :** This is not screening or screening information

**Commentaire [JPT3] :** This row might still be sustained, as this is about the use of screening information for screening assessment

**Commentaire [JPT4] :** This not screening information, hence removed

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

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

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. A prerequisite for this choice is that he fulfils the conditions of exposure based adaptation of, Section 3.2(b) and (c) of Annex XI to REACH. The registrant must report accordingly in the CSR and in the safety data sheet (SDS) this status and follow all obligations set for a substance which based on available information is considered to meet the PBT or vPvB criteria. 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.1.5.1).

**Commentaire [JPT5] :** The "as i fit is a PBT or vPvB" is now two times in this guidance, it is a good question whether this is too much repetition or not.

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.1.5.2).

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 EC10 from long-term toxicity tests with aquatic organisms (see Section C.1.5.3).

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 sometimes be more reasonable to start the PBT/vPvB assessment by evaluating the B criterion (see Section R.11.4.2 for further guidance).

The registrant must continue the cycle of generation of relevant additional data 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.1.4 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"[5]

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).

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 amounts ≥0.1 % (w/w) are being generated, the substance must be subjected to PBT/vPvB specific emission characterisation and risk characterisation. However, for the sake of relevance of risk exerted by the amount of a *PBT/vPvB substance* manufactured/imported by a registrant, and hence with regard to the requirements for risk characterisation and nature of RMMs to be implemented, it may be considered to use a threshold value of 10% (w/w) for the total of all constituents or transformation/degradation products being *PBT/ vPvB substances*, if it is possible to estimate with sufficient certainty that the total manufacture/import or supply of *PBT/vPvB constituents* in that substance and the total amount of degradation/transformation products being *PBT/vPvB substances* generated by that substance do not exceed 1 t/y[6]. In the considerations as to whether application of this percentage trigger could be appropriate, the use pattern of the substance and the potential emissions of the constituents or transformation/degradation products being themselves *PBT/vPvB substances* must be accounted for.

The main objective of the emission characterisation is to estimate the amounts 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[7]. 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 provide guidance on how to develop ESs for substances in general.

---

5 For the purpose of this section including the subsections, 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".

6 Please note that the proposed one tonne per year threshold for the total of compounds with PBT/vPvB properties in a substance consisting of more than one component (be it a mixture or a multi-constituent substance) is not an 'allowable release' threshold. It refers instead to the content in a substance that will need to have appropriate risk assessment and management justified in the chemical safety report. 1 t/y is the level at which the registration requirement under REACH normally begins to apply if a substance was supplied alone or in a mixture. 1 t/y is also the trigger for registration in an article. Therefore, this amount is considered to be a suitable threshold level for relevance and hence adaptation of required risk assessment efforts and, depending on the results of risk assessment, possibly risk management measures.

7 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.

## Part C: PBT and vPvB assessment

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. kg/year) to the different environmental compartments during all activities carried out during manufacture or identified uses (see Section R.11.3.6.1 for further guidance).

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 or 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 to a *PBT/vPvB substance* are, for instance, substitution of the substance or reduction of its use when technically possible, manufacture and use under strictly controlled conditions and handling of the substance by trained personnel only (see Section R.11.3.6.2 for further guidance).

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.

# C.1.5 Test strategies

## C.1.5.1 Persistence

The detailed testing strategy on degradation for PBT/vPvB assessment is set out in Section R.11.4.1 and Figure R.11-1. It is based on a weight of evidence approach starting with the review of all available screening test data and non-test data ((Q)SAR model predictions, read-across, and chemical categorisation). The criteria for the screening methods are given in Table C1-2. In some cases, the performance of an enhanced ready biodegradation test may deliver sufficient information to draw the conclusion that the substance can be considered as "not P".

If persistence cannot be excluded, it should be determined which compartments are likely to be exposed, and hence which simulation tests need to be conducted. This determination of the compartments(s) for simulation testing should take account of the intrinsic properties of the substance (e.g. water solubility, vapour pressure, log Kow, solid-water partition coefficient Kp, octanol–air partition coefficient Koa, half-life in air) that significantly influence the environmental fate of the substance. Multi-media modelling (e.g. Mackay level 3 models) may also be used in order to determine the environmental compartment(s) of primary concern.

Soil/sediment simulation degradation testing is warranted if the screening data indicate potential persistence and direct or indirect exposure of these compartments is likely. This includes cases where a substance is released to surface water but due to high sorption partitions to sediment or sewage sludge, which may be spread on soil, or where a substance is volatilised from water to air and deposited to soil.

The Kp (sediment) may be used as an indicator of whether testing in a water-sediment system may be warranted. For example, it may be considered to conduct an aquatic sediment simulation test in addition to a pelagic simulation test for substances with Kp (sediment) > 2000.

## C.1.5.2 Bioaccumulation

A detailed test strategy for bioaccumulation testing for PBT/vPvB assessment is set out in Section R.11.4.2 and Figure R.11-2. 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.11.4.2).

If the above-mentioned information is not available and the substance has a log Kow ≤ 4.5 and no specific uptake mechanism apart from lipophilic partitioning is known or suspected and no other indications of accumulation are present, 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 bioconcentration are available and the substance has a log Kow > 4.5, or the partitioning process into aquatic organisms is not driven by 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;

the B and vB properties should be evaluated in more detail.

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 invertebrates, or reliable read-across from a structurally similar compound. Evidence of significant uptake of a substance in fish or mammals after prolonged exposure is a contraindication to using the above indicators of limited bioconcentration.

### C.1.5.3 Toxicity

A detailed test strategy for toxicity testing for PBT/vPvB assessment is set out in Section R.11.4.1.3 and Figure R.11-3. 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[8] is met, the substance fulfils the T criterion[9] 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)C50 value from a standard toxicity (or reliable non-standard) test is <0.01 mg/l. When the L(E)C50 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[10], 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 EC10 close to but above 0.01 mg/l, a long-term fish study is likely to be needed to confirm “not T”.

For certain 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/EC10 <0.01 mg/l cannot be excluded even if

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

9 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.

10 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 EC50) is derived.

available short-term toxicity data indicate L(E)C50 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.11-3 and decision tree Steps 2, 5 & 6).

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

## C.1.6 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 (see Section R.11.4.4 for further guidance).

(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 PBT or vPvB criteria or do not allow a direct comparison with all the criteria but nevertheless provide reliable evidence that the substance does not behave in the environment in the same way as substances which fulfil the criteria based on direct comparison with the criteria or, if only screening information is available, it indicates in absence of counter evidence that it is unlikely that the criteria are fulfilled.

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[11] (see Section C.1.1).

(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 Annex XIII to REACH, or do not allow a direct comparison with all the criteria in Annex XIII, but nevertheless provide reliable evidence that the substance behaves in the environment in the same way as substances which fulfil the criteria based on direct comparison 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.

(iii) Further information for the PBT assessment is necessary. The available data is not sufficient for concluding (i) or (ii). The substance may have PBT or vPvB properties or it cannot be reliably excluded that the substance has PBT or vPvB properties.

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

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 lacking 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) would have been drawn.

**European Chemicals Agency**
P.O. Box 400, FI-00121 Helsinki
http://echa.europa.eu