



# TECHNICAL GUIDANCE DOCUMENT FOR PREPARING THE CHEMICAL SAFETY ASSESSMENT

## Part C

### PBT Assessment

**“Technical Guidance Documents in support of the New EU Chemicals Legislation (REACH) –  
V: Development of a Technical Guidance Document for preparing the Chemical Safety  
Assessment (REACH Implementation Project 3.2-2)”**

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## 1 **C.1 PBT AND vPvB ASSESSMENT**

2 A PBT/vPvB assessment is required for all substances for which a Chemical Safety Assessment  
3 (CSA) must be conducted. These are in general all substances manufactured or imported in amounts  
4 of 10 or more tonnes per year that are not exempted from registration under REACH. However,  
5 some further exemptions apply, e.g. substances present in a preparation if the concentration is less  
6 than 0.1 % weight by weight (Article 14(2)), for on-site isolated (Art. 17) or transported  
7 intermediates (Art. 18), and for Product and Process Oriented Research and Development (Art. 9)  
8 (see RIP 3.1 Guidance on registration, section 1.8.1, for further information).

### 9 **C.1.1 Aim and procedure**

10 The objective of the PBT/vPvB assessment is to determine in a stepwise procedure:

- 11 1. Whether the substance fulfils the criteria given in Annex XIII (comparison with the criteria) .  
12 If it is concluded that the substance is not a PBT/vPvB substance, the PBT/vPvB assessment  
13 stops after comparison with the criteria. An exposure and risk assessment as for a non-  
14 PBT/vPvB substance could however be required if the substances is dangerous in accordance  
15 with the classification criteria of Council Directive 67/548/EEC.
- 16 2. If a substance is confirmed to be a PBT/vPvB substance, the registrant needs in a second step  
17 (emission characterisation) to estimate the amounts of the substance released to the different  
18 environmental compartments during all activities carried out by the registrant and all identified  
19 uses. In addition, it is necessary to identify the likely routes by which humans and the  
20 environment are exposed to the substance.
- 21 3. The registrant shall use the information obtained during the emission characterisation step, for  
22 implementing on his site, and recommending to downstream users, Risk Management Measures  
23 (RMM) which minimise emissions and subsequent exposures of humans and the environment  
24 throughout the lifecycle of the substance that results from manufacture or identified uses.

### 25 **C.1.2 PBT and vPvB criteria**

26 A substance that fulfils all three of the criteria for persistence, bioaccumulation and toxicity  
27 described in Table 1 is a PBT substance.

28 It should however be noted that, even where a criterion is marginally not fulfilled, the overall  
29 evidence can be sufficient to justify the conclusion that a substance fulfils the Annex XIII criteria.  
30 This includes for example substances that do not fulfil the persistence criteria but bioaccumulate  
31 significantly and are measured in increasing levels over time in biota distant from anthropogenic  
32 sources (see section R.11.1.5 for further guidance).

### 33 **C.1.3 Comparison with the PBT and vPvB criteria**

34 The PBT and vPvB assessment of a substance shall be based on all the relevant information  
35 available, which is normally the information that shall be submitted as part of the technical dossier,  
36 including the physicochemical, hazard and exposure information generated in the context of the  
37 CSA. If the technical dossier, for one or more endpoints, contains only the information as required

38 in Annexes VII and VIII, the registrant shall, based on screening criteria or other information  
39 available, consider whether further information needs to be generated to fulfil the objective of the  
40 PBT and vPvB assessment, i.e to assess whether the substance fulfils the criteria. Hence, it is task of  
41 the registrant to assess if the information that is available and/or produced is sufficient to conclude  
42 whether the substance is a PBT or a vPvB substance or not. In many cases further information as  
43 detailed in Annexes IX and X of the Regulation may need to be generated before it can be judged  
44 whether the substance fulfils the Annex XIII criteria. Generally, before generating information  
45 detailed in Annexes IX and X, a testing proposal needs to be submitted to and authorised by the  
46 European Chemicals Agency.

47 The PBT assessment is initiated by an evaluation of all available information. For substances below  
48 a volume of 100 t/a normally data on ready biodegradability, octanol-water partitioning coefficient  
49 (log Kow) and environmental toxicity are available that give an indication on the P, B and T  
50 properties of a substance.

51 Table C.1-2 gives an overview of information that can be used for a screening assessment and  
 52 provides criteria to decide whether an in depth assessment on the PBT or vPvB properties is  
 53 necessary.

54 When the screening criteria do not clearly indicate that there is no concern that the substance could  
 55 meet the Annex XIII criteria (Table C.1-1), a stepwise approach is followed for the definitive  
 56 assessment of the P, B and T criteria, which is further outlined below.

57 **Table C.1-1: PBT and vPvB criteria according to Annex XIII of the REACH Regulation**

Property	PBT-criteria	vPvB-criteria
<b>Persistence<sup>1</sup></b>	<ul style="list-style-type: none"> <li>- <math>T_{1/2} &gt; 60</math> days in marine water, or</li> <li>- <math>T_{1/2} &gt; 40</math> days in fresh- or estuarine water, or</li> <li>- <math>T_{1/2} &gt; 180</math> days in marine sediment, or</li> <li>- <math>T_{1/2} &gt; 120</math> days in fresh- or estuarine sediment, or</li> <li>- <math>T_{1/2} &gt; 120</math> days in soil.</li> </ul>	<ul style="list-style-type: none"> <li>- <math>T_{1/2} &gt; 60</math> days in marine, fresh- or estuarine water, or</li> <li>- <math>T_{1/2} &gt; 180</math> days in marine, fresh- or estuarine sediment, or</li> <li>- <math>T_{1/2} &gt; 180</math> days in soil.</li> </ul>
<b>Bioaccumulation<sup>2</sup></b>	BCF > 2000 L/kg	BCF > 5000 L/kg
<b>Toxicity</b>	<ul style="list-style-type: none"> <li>- NOEC &lt; 0.01 mg/L for marine or freshwater organisms, or</li> <li>- substance is classified as carcinogenic (category 1 or 2), mutagenic (category 1 or 2), or toxic for reproduction (category 1, 2 or 3), or</li> <li>- there is other evidence of chronic toxicity, as identified by the classifications: T, R48, or Xn, R48 according to Directive 67/548/EEC.</li> </ul>	-

58 Screening assessment

59 The screening criteria (Table C.1-2) should always be considered in conjunction for P, B and T to  
 60 decide whether the substance has to be regarded as a potential PBT/vPvB. It has to be kept in mind  
 61 that the fact that a substance does not meet the T criterion is not enough to stop the evaluation of the  
 62 remaining endpoints in the PBT/vPvB screening step.

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**Table C.1-2: Screening criteria for Persistency, Bioaccumulation, and Toxicity**

Type of data	Criterion	Screening assignment
<b>Persistence</b>		
Ready biodegradability test	Readily biodegradable	Not P and not vP
Enhanced ready biodegradability test	Readily biodegradable	Not P and not 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
MITI II test (OECD 302C)	≥ 70% mineralisation (O <sub>2</sub> uptake) within 14 days; log phase no longer than 3d; no pre-adapted inoculum	Not P
Biowin 2 (non-linear model prediction) and Biowin 3 (ultimate biodegradation time)  <b>or</b> 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)  <b>or</b> Does not biodegrade fast (probability <0.5) and ultimate biodegradation timeframe prediction: ≥months (value < 2.2)	P  P
<b>Bioaccumulation</b>		
Convincing evidence that a substance can biomagnify in the food chain (e.g. field data)	e.g. BMF > 1	B or vB, definitive assignment possible
Octanol-water partitioning coefficient (experimentally determined or estimated by QSAR)	Log K <sub>ow</sub> ≤ 4.5	not B and not vB
<b>Toxicity</b>		
Short-term aquatic toxicity	EC <sub>50</sub> or LC <sub>50</sub> < 0.01 mg/L	T, criterion considered to be definitely fulfilled
Short-term aquatic toxicity	EC <sub>50</sub> or LC <sub>50</sub> < 0.1 mg/L	T
Avian toxicity (subchronic or chronic toxicity or toxic for reproduction)	NOEC < 30 mg/kg food	T

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Definitive assessment

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If, on the basis of the screening assessment, a substance is considered to potentially fulfil the criteria for P, B and T or for vP and vB, the registrant may choose to treat the substance as a PBT/vPvB-substance and report accordingly in the chemical safety report without further evaluation of the properties.

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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 should be conducted first. Definitive assessment of P/vP should normally be based on half-life data collected under adequate conditions for the relevant compartment(s) of exposure (see section C.C.1.4.1).

73 If the substance is considered to fulfil the P and/or vP criterion, the PBT/vPvB assessment is  
74 continued by evaluation of the B/vB criterion. Definitive assessment of B/vB should normally be  
75 based on measured data on bioconcentration in aquatic species (see section C.C.1.4.2).

76 If the substance is not identified as vPvB but considered to fulfil the P and B criteria, the PBT  
77 assessment is continued by evaluation of the T criterion. Definitive assessment of T should be based  
78 on evaluation of the data for classification of the substance for human health hazards and/or on no-  
79 observed effect concentration(s)(NOECs) from long-term toxicity tests with aquatic organisms (see  
80 section C.C.1.4.3).

81 However, for substances for which persistency testing is difficult or practically impossible, like e.g.  
82 for certain multi-constituent or very poorly water soluble substances, it may sometimes be more  
83 reasonable to start the PBT/vPvB assessment by evaluating the B criterion (see sections R.11.1.1 &  
84 R.11.1.3.2 for further guidance).

## 85 **C.1.4 Test strategies**

### 86 **C.1.4.1 Persistency**

87 The detailed testing strategy on degradation for PBT/vPvB assessment is set out in section  
88 R.11.1.3.1 and Figure R.11-1. It is based on a weight of evidence approach starting with the review  
89 of all available screening test data and non-test data ((Q)SAR model predictions, read across, and  
90 chemical categorisation). The criteria for the screening methods are given in Table C.1-2. In some  
91 cases, the performance of an enhanced ready biodegradation test may deliver sufficient information  
92 to draw the conclusion that the substance can be considered as "not P".

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

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

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

### 108 **C.1.4.2 Bioaccumulation**

109 A detailed test strategy for bioaccumulation testing for PBT/vPvB assessment is set out in section  
110 R.11.1.3.2 and Figure R.11-2. In general, all existing information on the bioaccumulation potential  
111 of a substance should be collected and evaluated first before a decision on the necessity to conduct  
112 further testing is drawn. The existing data may include laboratory bioconcentration tests (aquatic,

113 terrestrial and benthic) and field studies on biomagnification or bioaccumulation. Such available  
114 information might be sufficient to conclude whether the substance is vB, B, or not B (see Section  
115 R.11.1.3.2).

116 If the above mentioned information is not available for a substance produced or imported at a level  
117 of less than 100 t/y and the substance has a  $\log K_{ow} \leq 4.5$  and no specific uptake mechanism apart  
118 from lipophilic partitioning is known, then the substance can be considered as not B and not vB and  
119 further evaluation of the B and vB criteria is not necessary.

120 However, for a substance produced or imported at a level of 100 t/y or more, information on  
121 bioconcentration in aquatic species has to be made available by the registrant and to be considered  
122 in the assessment, unless this information can be waived according to column 2 of Annex IX or  
123 according to Annex XI(3) (e.g low bioaccumulation potential, no exposure, testing technically not  
124 possible).

125 In other cases, where:

- 126 • no direct data on bioconcentration are available and the substance has a  $\log K_{ow} > 4.5$ , or the  
127 partitioning process into aquatic organisms is not driven by lipophilicity ;
- 128 • direct data on bioconcentration are available but these data are not reliable and/or consistent to  
129 a degree sufficient to conclude whether the B or vB criteria are met;

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

131 In this further evaluation, non-testing data should be used as indicators for limited bioaccumulation  
132 in a weight of evidence assessment together with supplementary information to examine whether  
133 the substance potentially meets the B and vB criteria. Because the indicators for limited  
134 bioaccumulation (e.g. molecular weight and size of the molecule, octanol solubility or  $\log K_{ow}$ ) are  
135 on their own considered to be insufficient to abstain from confirmatory testing, the availability of  
136 other reliable information indicating a low bioaccumulation potential is essential. This  
137 supplementary information may comprise data showing no toxicity in a chronic toxicity study with  
138 mammals, no uptake in a toxicokinetic study, or it could be a bioconcentration study with  
139 invertebrates or reliable read-across from a structurally similar compound. Evidence of significant  
140 uptake of a substance in fish or mammals after prolonged exposure is a contraindication to using the  
141 above indicators of limited bioconcentration.

#### 142 **C.1.4.3 Toxicity**

143 A detailed test strategy for toxicity testing for PBT/vPvB assessment is set out in Section R.11.1.3.3  
144 and Figure R.11-3. The strategy starts with the evaluation of the classification of the substance. If  
145 any classification criterion leading to the assignment of the R-phrases R45, R46, R48, R49, R60 –  
146 R64 is met, the substance fulfils the T criterion<sup>1</sup> and there is no need to perform any further aquatic  
147 studies for T assessment.

148 When no such classification is assigned, data on aquatic toxicity should be evaluated. When no  
149 chronic toxicity data are available, a substance is considered to meet the T-criterion when an acute  
150 L/EC50 value from a standard toxicity (or reliable non-standard) test is  $< 0.01$  mg/l. When the  
151 L/EC50 is  $< 0.1$  mg/l, the substance is considered to meet potentially the T-criterion, and

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<sup>1</sup> 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 R-phrases has already been assigned to the substance.

152 consequently the substance is referred to definitive T testing and chronic studies are required  
153 (regardless of the tonnage band). Note however that, due to animal welfare concerns, the general  
154 scheme of testing and confirming first P and B should be applied before further T-testing is  
155 considered. Also, vertebrate-animal testing should be minimised by first testing non-vertebrate  
156 species. Normally, the testing order for conclusion on T based on chronic data is Daphnia and then  
157 fish<sup>2</sup>, unless there is evidence that fish are more sensitive than daphnia. If the T-criterion is fulfilled  
158 by the chronic algae or Daphnia data, a chronic fish test is not necessary. If however a long term  
159 test on Daphnia or algae provides a NOEC close to but above 0.01 mg/l, a long-term fish study is  
160 likely to be needed to confirm “not T”.

161 For certain lipophilic substances (with a log Kow >5) acute toxicity may not occur at the limit of  
162 the water solubility of the substance tested (or the highest concentration tested). In such situations,  
163 chronic toxicity with a NOEC <0.01 mg/l cannot be excluded even if available short-term toxicity  
164 data indicate L/EC50 values > 0.1 mg/l, because these substances may not have had sufficient time  
165 in the acute test to be significantly taken up by the test organisms and to reach equilibrium  
166 partitioning. (see Section R.11.1.3.3, ITS for T-testing, Figure R.11-3 and decision tree Steps 2, 5 &  
167 6).

168 In the absence of definitive information on T, for substances with very high lipophilicity, a weight  
169 of evidence or group approach for long term toxicity may be used to predict whether long term  
170 effects are likely to occur. If convincing evidence is available that aquatic toxicity is not expected to  
171 occur at <0.01 mg/l, chronic testing may not be required. Such evidence could comprise reliable  
172 QSAR predictions, read-across or grouping approaches indicating narcotic mode of action together  
173 with measured low chronic fish toxicity data from a related compound. Supporting information  
174 could be chronic data on aquatic species such as, e.g., daphnids, algae or sediment dwelling species  
175 and/or low acute or chronic mammalian and avian toxicity. Any conclusions on the suitability of  
176 data and the T criterion should be based on expert judgement and weight of evidence. If data from  
177 this approach provide insufficient evidence that toxicity will not occur in a chronic test long-term T-  
178 testing must be considered.

### 179 **C.1.5 Conclusions on PBT or vPvB properties**

180 A detailed analysis of the persistence, bioaccumulation and toxicity should be brought together into  
181 a clear conclusion on whether the substance should be treated as a PBT/vPvB substance. There are a  
182 number of conclusions from this comparison that call for different responses from a registrant (see  
183 Section R.11.1.5 for further guidance).

184 (i) The data show that the properties of the substance meet the specific criteria detailed in Annex  
185 XIII, or do not allow a direct comparison with all the criteria in Annex XIII, but nevertheless  
186 indicate that the substance would have these properties

187 In this case an emission and risk characterisation for PBT/vPvB substances in accordance with  
188 the stipulations of Annex I is required.

189 (ii) The data show that the properties of the substance do not meet the specific criteria detailed in  
190 Annex XIII or do not allow a direct comparison with all the criteria in Annex XIII but

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2 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.

191 nevertheless indicate that the substance would not have these properties and the substance is  
192 not considered a PBT/vPvB

193 In this case the PBT/vPvB assessment stops at this point. An exposure assessment and risk  
194 characterisation as for a non-PBT/vPvB substance may however be required if the substance is  
195 dangerous in accordance with the classification criteria of Council Directive 67/548/EEC.

196 (iii) The data on the properties of the substance do not allow a direct comparison with all the  
197 criteria in Annex XIII and further information is needed

198 In this case a registrant has two options:

- 199 • The registrant generates the required information (depending on the information needed, the  
200 submission of a testing proposal may be required) and concludes on the PBT/vPvB  
201 properties of the substance concerned once the lacking data are available (i.e. conclusion (i)  
202 or (ii)); or
- 203 • The registrant refrains from generating further information and treats his substances as if it  
204 were a PBT/vPvB.

205 (iv) Further information would be needed to conclude on the PBT/vPvB properties of the  
206 substance. However, the registrant (for several reasons) has decided not to conduct  
207 confirmatory testing.

208 If a clear decision on the properties of a substance cannot be made, either because it is not  
209 possible to characterise a substance, or since it is technically not possible to conduct testing,  
210 this lack of a clear decision does not obviate the requirement on a registrant to propose  
211 appropriate and proportionate RMMs and OCs.

### 212 **C.1.6 Further actions if a substance is identified as a PBT or a vPvB**

213 If it is concluded that the substance is a PBT or vPvB substance, or that it should be treated as such,  
214 the registrant must conduct an emission characterisation and a risk characterisation for PBT/vPvB  
215 substances in accordance with Article 14 (4).

216 Generally, if a substance contains one or more constituents with PBT/vPvB properties in individual  
217 amounts  $\geq 0.1$  % (w/w) or if transformation/degradation products with the respective properties in  
218 amounts  $\geq 0.1$  % are being generated, the substance must be subjected to PBT/vPvB specific  
219 emission characterisation and risk characterisation. However, for the sake of relevance of risk  
220 exerted by the amount of a PBT/vPvB substance manufactured/imported by a registrant, and hence  
221 with regard to the requirements for risk characterisation and nature of RMM to be implemented, it  
222 may be considered to use a threshold value of 10% (w/w) for the total of all constituents or  
223 transformation/degradation products having PBT or vPvB properties, if it is possible to estimate  
224 with sufficient certainty that the total manufacture/import or supply of PBT/vPvB constituents in  
225 that substance and the total amount of degradation/transformation products with PBT/vPvB  
226 properties generated by that substance do not exceed 1 tonne/year<sup>3</sup>. In the considerations as to

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3 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 preparation 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/a is the level at which the registration requirement under REACH normally begins to apply if a substance was supplied alone or in a preparation. 1 t/a 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.

227 whether application of this percentage trigger could be appropriate, the use pattern of the substance  
228 and the potential emissions of the constituents or transformation/degradation products having PBT  
229 or vPvB properties must be accounted for.

230 The main objective of the emission characterisation is to estimate the amounts of the substance  
231 released to the different environmental compartments and to identify the likely routes by which  
232 humans and the environment are exposed to the substance. A registrant has only to take care of his  
233 own tonnage. In co-operation with his downstream users he has to cover, where relevant, any  
234 manufacture in the EU he is responsible for, his own uses and all identified uses including all  
235 resulting lifecycle stages.

236 The principal tool to achieve this objective are exposure scenarios (ES(s)). Part D and Chapters  
237 R.12 – R.18 provide guidance on how to develop ESs and to conduct the parts of an exposure  
238 estimation relevant for PBT/vPvB substances (i.e. emission estimation and assessment of chemical  
239 fate and pathways). In the context of the emission characterisation, the registrant needs to develop  
240 ES(s) for all identified uses of his PBT/vPvB substance, unless he concludes to advise in his  
241 technical dossier (and SDS) against certain uses of his substance. In this latter case he does not need  
242 to perform an emission characterisation or other risk management work related to these uses.

243 As PBTs and vPvBs are substances of very high concern, the registrant shall pay special attention to  
244 the level of detail of his assessment and whether its accuracy and reliability is sufficient for a  
245 PBT/vPvB substance. Where generic scenarios and assumptions may be sufficient for exposure  
246 assessment of non PBT/vPvB-substances, specific scenarios and data will most likely be needed  
247 throughout an emission characterisation for PBT/vPvB-substances. All effort necessary should be  
248 made to acquire for manufacture and any identified use throughout the lifecycle, site- and product-  
249 specific information on emissions and likely routes by which humans and the environment are  
250 exposed to the substance. The emission characterisation shall in particular be specific in the use  
251 description and concerning RMMs, and shall furthermore contain an estimation of the release rate  
252 (e.g. kg/year) to the different environmental compartments during all activities carried out during  
253 manufacture or identified uses (see Section R.11.2.1 for further guidance).

254 The objective of a risk characterisation for substances satisfying the PBT or vPvB criteria is to use  
255 the information obtained in the emission characterisation step to implement on a registrant's site or  
256 to recommend to his downstream users RMMs which minimise exposures and emissions to humans  
257 and the environment throughout the lifecycle of the substance that results from manufacture or  
258 identified uses (Annex I (6.5)). To this end, the minimisation of exposures and emissions to humans  
259 and the environment needs to be considered throughout the development of ES(s). The need or a  
260 potential to (further) minimise emissions or exposure may therefore be recognised at any point in  
261 the development of an ES. In this way, the appropriateness and effectiveness of RMMs and OCs  
262 should be assessed in the iterative refinement process of the ES.

263 Suitable options and measures to minimise emissions of and exposure to a PBT/vPvB substance are,  
264 for instance, substitution of the substance or reduction of its use when technically possible,  
265 manufacture and use under strictly controlled conditions and handling of the substance by trained  
266 personal only (see Section R.11.2.2 for further guidance).

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