



# TECHNICAL GUIDANCE DOCUMENT FOR PREPARING THE CHEMICAL SAFETY ASSESSMENT

## Chapter R.12: Exposure Based Waiving

**“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)”**

**Service Contract Number CCR.IHCP.C432365.X0**



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## 1 **R.12 EXPOSURE BASED WAIVING**

### 2 **R.12.1 INTRODUCTION**

3 REACH requires the generation of information on substances through testing and by  
4 other means: read-across from structurally related compounds and the use of QSARs,  
5 and by alternatives to animal testing such as *in vitro* methods. In situations where  
6 human or environmental exposure is absent or so low that additional effects  
7 information will not necessarily lead to improvement of risk management, exposure  
8 based-waiving may be considered. This is included in step 3 of the general decision  
9 making framework in Chapter R.2.

10 REACH allows that certain tests may be waived based on the absence of exposure or  
11 unlikely, no relevant or no significant exposure. These provisions were included to  
12 avoid unnecessary animal testing. Based on adequate information on exposure, a  
13 decision can be taken whether it is possible to waive tests, or if further testing should  
14 be proposed, or if more stringent RMMs need to be introduced. Exposure based  
15 waiving (EBW) in this context is defined as an omission from the standard  
16 information requirement at the actual tonnage level based on exposure arguments. The  
17 Commission shall adopt the criteria defining what constitutes adequate justification by  
18 1 Dec 2008.

19 In addition to waiving, toxicological testing may be adapted by selection of  
20 appropriate exposure route based on relevant human exposure. This will not be  
21 discussed further in this document. Contrary to waiving, Column 2 entries in Annex  
22 VII-X can also indicate that additional testing can be triggered if the chemical safety  
23 assessment indicates the need to investigate further the effects on humans or the  
24 environment. This is an integrated part of the chemical safety assessment and the  
25 possible iterations to demonstrate control of risks.

26 This guidance addresses EBW, its terminology and when it is appropriate (Section  
27 12.2), the conditions for EBW (Section 12.3), how this should be justified (Section  
28 12.4) and documented in the IUCLID5 dossier and the chemical safety report (at  
29 tonnage levels  $\geq 10$  tonnes per year, Section 12.5).

30 This justification can be based on:

- 31 • 'Column 2 route for EBW'. Cases where it is proposed that exposure based  
32 waiving of testing should be considered based on column 2 of Annexes VIII-X. A  
33 qualitative argumentation can be applied (unless reference is made to Annex XI in  
34 Column 2) when it is argued that exposure is low or not relevant, e.g. due to the  
35 specific uses of a substance. In most of these cases, a weight of evidence approach is  
36 needed to justify waiving (see section R.4.4 and R.7).
- 37 • 'Annex XI route for EBW'. Cases where it is proposed that exposure based  
38 waiving of testing should be considered, based on the general rules for adaptation of  
39 the standard testing regime (Annex XI), substance-tailored exposure driven testing  
40 (Annex XI(3)). Here it is stated that *'testing may be omitted according to REACH  
41 based on the exposure scenarios developed in the Chemical Safety Report. In all cases  
42 adequate justification and documentation shall be provided'*. In these cases, a  
43 quantitative argumentation needs to be provided, based on the exposure scenario  
44 developed in the Chemical Safety Report. The requirements for this are mentioned in  
45 Section 12.4.

46 Waiving for a specific endpoint should be documented in the IUCLID 5 dossier.  
47 When the argumentation is built on the use of Exposure scenarios, the documentation  
48 in IUCLID 5 should refer to the Chemical Safety Report (see Section 12.5).

## 49 **R.12.2 GUIDING PRINCIPLES**

### 50 **R.12.2.1 Terminology on waiving**

51 REACH uses different terms in relation to exposure based waiving in column 2  
52 adaptations of Annexes VIII-XI, where the precise wording is given in Section 12.3.  
53 Different types of terminology are used, summarized based on a previous analysis  
54 (NOIS 2007):

- 55 • In Column 2 adaptations, terminology is used indicating absence of exposure  
56 ('relevant exposure can be excluded' or 'no exposure').
- 57 • In Column 2 adaptations, terminology is used indicating that exposure is unlikely  
58 (i.e. not 'absent' or 'excluded'), or not significant ('limited exposure', 'no significant  
59 exposure').
- 60 • In Annex XI, there is no specific terminology indicating the degree of exposure,  
61 but specific tests may be omitted based on the exposure scenario(s) developed in the  
62 chemical safety report.

63 From the terminology overview, we will hereafter use the underlined words to  
64 indicate the different exposure situations. The following conclusions can be drawn:

65 Exposure based waiving is appropriate when exposure is absent or not significant. The  
66 justification whether this is appropriate lies with the registrant and can be done via  
67 two entries:

- 68 • 'Column 2 route to EBW' with a qualitative weight of evidence justification
- 69 • Annex XI(3) route for EBW' with a quantitative justification based on the  
70 exposure scenario(s) developed in the CSR.

71 In both cases, the justification should address the risks due to exposure, because a  
72 limited level of exposure in itself does not mean that the exposure and the associated  
73 risk is insignificant. The justification for EBW should either be based on a  
74 quantitative risk characterisation (according to Annex XI) or a qualitative assessment  
75 of the likelihood that effects are avoided. EBW differs from a normal risk  
76 characterisation due to the level of knowledge on hazard and exposure. For a certain  
77 endpoint a standard information requirement is omitted. This implies that a high level  
78 of confidence is needed to demonstrate no or no significant in order to justify this  
79 omission.

### 80 **R.12.2.2 Waiving is risk-based**

81 The interpretation in this guidance document is that exposure-based waiving of test  
82 requirements under REACH is risk based because it considers exposure in relation to  
83 hazard information on an endpoint. Therefore exposure information may have to be  
84 gathered even if performing an exposure assessment would not be required for the  
85 CSA according to article 14 (4), if no hazardous properties or PBT,vPvB  
86 identification are identified at this point in the hazard assessment.

87 This is the trade-off between doing the testing or obtaining better information on  
88 exposure to provide a qualitative or quantitative justification for EBW. Hazard data  
89 play a role in the risk-based decision making. For waiving of some endpoints,  
90 (especially for environmental effects from long-term exposure) hazard information  
91 may allow derivation of threshold levels or reference levels since data from short-term  
92 exposure or physical chemical properties might be used for extrapolation. For other  
93 endpoints (e.g. repeated dose toxicity and/or reproductive toxicity at Annex VIII  
94 levels), no toxicity data may be available.

95 When human or environmental exposure can be excluded it is relatively simple that  
96 due to absent or no significant exposure to a substance, the derivation of a DNEL or  
97 PNEC for a specific endpoint is superfluous since the outcome of the risk assessment  
98 will in any case be no significant risk. When exposure is low, the conclusion of 'no  
99 concern' in relation to a specific endpoint needs to be based on the risk associated  
100 with this level of exposure.

### 101 **R.12.2.3 Waiving needs consideration of the entire life cycle of a chemical**

102 In any EBW case, all relevant stages in the life-cycle of a chemical should be taken  
103 into account for a valid justification of waiving (see section 12.4). A prerequisite for  
104 EBW is the collection and evaluation of available knowledge on hazards of the  
105 substance, operational conditions of use over the whole life cycle and the identified  
106 uses of the substance. Extensive and detailed knowledge of exposure throughout the  
107 life cycle for human and environmental exposure is essential for exposure based  
108 waiving. Depending on the type of test that is waived, occupational exposure,  
109 consumer exposure and human exposure via the environment as well as exposure of  
110 all environmental compartments may need to be considered. If exposure can be  
111 excluded for a specific use (e.g. no consumer exposure) the whole life-cycle still has  
112 to be considered for exposure to workers or professional users in order to determine if  
113 waiving for a specific endpoint is appropriate.

## 114 **R.12.3 EXPOSURE BASED-WAIVING OPTIONS**

### 115 **R.12.3.1 Column 2 adaptations of Annexes VIII to X**

116 Annexes VI to X specify the information requirements for registration purposes. The  
117 following exposure-based waiving options exist, without precedence or priority of  
118 column 2 of Annexes VIII to X over Annex XI (3) or vice versa. It is possible to  
119 waive in accordance with adaptations in column 2 of Annexes VIII to X, and annex  
120 XI, section 3, provided the conditions laid down in that column are met (see Section  
121 12.3.1).

#### 122 *Human hazard*

- 123 • In Annexes VIII, repeated dose toxicity (28 d test, 8.6) and reproductive toxicity  
124 testing (8.7) may be waived '*if relevant human exposure can be excluded in  
125 accordance with Annex XI section 3*'
- 126 • In Annex IX, a sub-chronic toxicity test (90 d, 8.6.2) may be waived if 'the  
127 substance is unreactive, insoluble and not inhalable and there is no evidence of  
128 absorption and no evidence of toxicity in a 28-day "limit test", *particularly if such a  
129 pattern is coupled with limited human exposure*'.

- 130 • In Annex IX, a reproductive toxicity test (8.7) may be waived if the following  
131 combination applies: ‘the substance is of low toxicological activity (no evidence of  
132 toxicity seen in any of the tests available), it can be proven from toxicokinetic data  
133 that no systemic absorption occurs via relevant routes of exposure (e.g. plasma/blood  
134 concentrations below detection limit using a sensitive method and absence of the  
135 substance and of metabolites of the substance in urine, bile or exhaled air) *and there is*  
136 *no or no significant human exposure*’.
- 137 • In Annex X, the same conditions for exposure-based waiving of reproductive  
138 toxicity (8.7) testing as in Annex IX.
- 139

#### 140 *Environmental hazard*

- 141 • In Annex IX one of the arguments given for waiving simulation studies on  
142 terrestrial (section 9.2.1.3) or sediment micro-organisms (section 9.2.1.4) is ‘*if direct*  
143 *and indirect exposure of [soil][sediment] is unlikely*’.
- 144 • In Annex IX, bioaccumulation testing of fish (9.3.2) may be waived if ‘direct and  
145 indirect exposure of the aquatic compartment is *unlikely*’.
- 146 • In Annex IX, toxicity testing with soil organisms (9.4) may be waived ‘if direct  
147 and indirect exposure of the soil compartment is *unlikely*’
- 148 • In Annex X, long-term toxicity tests with soil organisms (9.4) may be waived ‘if  
149 direct and indirect exposure of the soil compartment is *unlikely*’.

150 It should be noted that the Annexes also mention cases where the results of the CSA  
151 indicate that exposure to humans or biota is likely (e.g., hazard quotients indicate that  
152 toxicological thresholds are exceeded). In cases of exposure based triggering, further  
153 testing may be required to reduce uncertainties on the outcome of the CSA in any  
154 direction (see the uncertainty analysis chapter R.19). The chemical safety assessment  
155 can indicate the need to further investigate at that tonnage level if the standard result  
156 of a test (belonging to the standard requirements of REACH for the relevant tonnage  
157 level) possibly could lead to a change regarding one of the following:

- 158 • classification or declassification  
159 • assignment as PBT/vPvB or not  
160 • concern or no concern.

161 When the answer is yes a need for further testing is indicated. If the answer is no,  
162 further testing is not warranted unless such need is indicated in some other way in the  
163 chemical safety assessment. Details on triggered testing for individual endpoints are  
164 further discussed in the weight of evidence and intelligent testing strategies (see the  
165 hazard guidance, Chapter R.7).

#### 166 **R.12.3.2 Substance-tailored exposure-driven testing (Annex XI (3))**

167 Annex XI of REACH gives general rules for adaptation of the standard testing regime  
168 of annex VII to X of REACH. The essential element for waiving based on Annex XI  
169 is the need for an exposure assessment and ensuing exposure scenario. It can be  
170 applied starting from Annex VIII requirements (substances imported or produced  
171 starting at 10 tonnes per year) with the following conditions:

- 172 • Testing according to Annex VIII (only sections 8.6 and 8.7), Annex IX and Annex  
173 X may be omitted, based on exposure scenario(s), containing information on exposure

174 and implemented risk management measures (cf. Article 13(1)) satisfying the  
175 principles of Section R.12.2.

176 • In all cases, adequate justification and documentation shall be provided. The  
177 justification shall be based on an exposure assessment in accordance with section 5 of  
178 Annex I and be consistent with the criteria to be developed.

179 • The conditions of use as specified in the ES must be communicated through the  
180 chemical supply chain via the SDS or otherwise if an SDS is not required (REACH  
181 article 32).

182

### 183 **R.12.3.3 In the context of notification of articles**

184 Although not within the scope of the Chemical Safety Assessment, exposure based  
185 waiving could be applicable to substances contained in articles (REACH Article 7(3))  
186 that are not released intentionally, but should be notified according to Article 7(2). A  
187 notification of substances of very high concern (SVHC), which are on the candidate  
188 list for authorisation and are contained in articles is not required, if exposure of  
189 humans and the environment can be excluded during normal or foreseeable  
190 conditions. The current guidance on waiving may be useful to determine if exposure  
191 to SVHC can be excluded according to Article 7(3). For further information, please  
192 consult the guidance on requirements for substances in articles.

## 193 **R.12.4 JUSTIFICATION FOR EXPOSURE BASED WAIVING**

### 194 **R.12.4.1 Introduction**

195 The justification for waiving should be based on information on hazard, exposure and  
196 the operational conditions and implementation of risk management measures  
197 satisfying the above mentioned guiding principles. In order to demonstrate no or no  
198 significant exposure it is necessary to carry out a detailed exposure assessment. A  
199 framework is presented to systematically consider the different options for developing  
200 waiving argumentation and documentation (Figure 1). The different assessment steps  
201 are discussed in the next sections.

### 202 **R.12.4.2 Collection of hazard and exposure information**

203 The first step in the assessment starts when the initial hazard information has been  
204 collected. All available hazard information should be evaluated before deciding on the  
205 need for waiving.

206 The second step is to consider the life-cycle of the substance and the identified uses of  
207 the substance in the market of the substance based on existing in-house information.  
208 The different uses can be described by using the harmonised descriptor system.

209 The next thing to do is to systematically consider exposure routes and potential  
210 exposure to humans or the environment. Exposure to a specific or general population  
211 or environmental compartment may be absent and could be a reason for waiving a  
212 specific test. However, exposure may still be an issue during the remainder of the life-  
213 cycle implying that the test would still be required. Detailed information should be  
214 collected for lifecycle steps which may trigger exposure related to specific

215 populations or targets (occupational, environmental, consumer exposure and exposure  
216 of humans via the environment) before a test can be waived:

217 • Use of a substance on its own, in preparations or in articles: manufacture of  
218 substances or production of articles, synthesis, processing aid etc., and resulting waste  
219 stages.

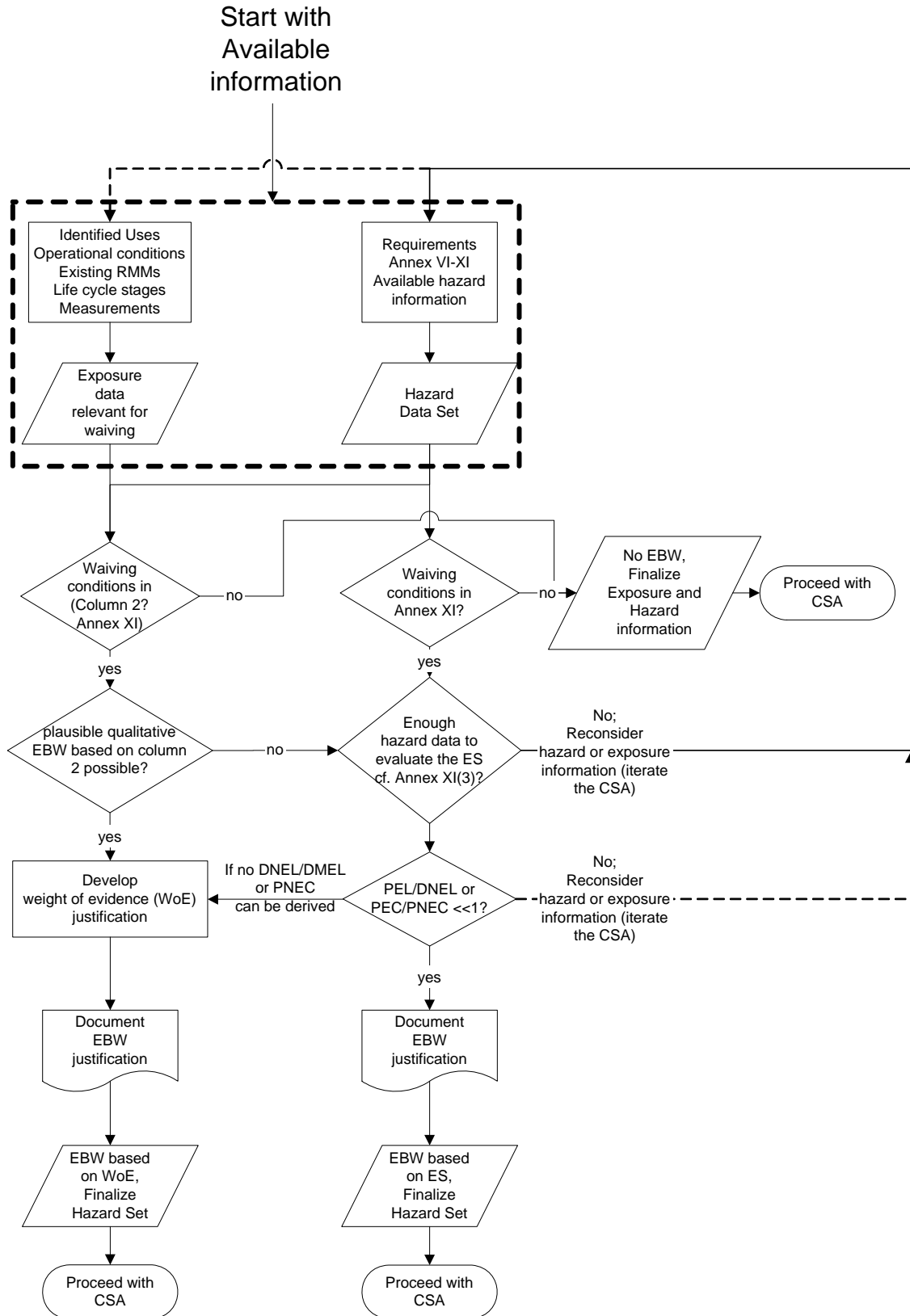
220 • Incorporation of the substance into articles and resulting service-life and waste  
221 stages

222 In addition, the operational conditions and risk management measures that apply to  
223 the identified uses of a substance should be considered, since these are used to  
224 document the exposure situation. As a general rule it will be difficult to justify EBW  
225 for a substance with a wide spectrum of uses since it will be difficult to demonstrate  
226 that the risks are adequately controlled for all these uses throughout the life-cycle.

227 Several formats are designed for targeting the assessment and summarizing uses and  
228 exposure pathways that could be used for this purpose (Section D, Table D-8 and D-  
229 9).

230  
231  
232  
233

**Figure R.12-1: Flow diagram for deciding on exposure-based waiving (EBW) or exposure-based testing (EBT), depending on collection of information on hazard and exposure.**



234

### 235 **R.12.4.3 Waiving conditions and options**

236 The next step is to define if waiving of a study is appropriate and under which  
237 conditions (see Section 12.3). The registrant should decide if waiving is based on  
238 column 2 entries to Annex VIII-X or on Annex XI entries. If insufficient hazard  
239 information is available, it may not be possible to quantitatively evaluate the hazard  
240 data against the exposure estimates linked to an exposure scenario. Then, further CSA  
241 iterations are needed or it may be possible to qualitatively argue that waiving is  
242 appropriate. If waiving conditions do not apply, the normal procedure is followed in  
243 the hazard assessment for the relevant endpoint(s), see the hazard guidance, Chapter  
244 R.7.

### 245 **R.12.4.4 Column 2 -Qualitative justification for exposure-based waiving**

246 For all justifications, it is key that it will be documented on what grounds the waiving  
247 is applied (based on which REACH section), and how it was decided to waive based  
248 on exposure information, e.g. can the waiving be documented on qualitative  
249 arguments (Column 2 adaptations). As part of a qualitative argumentation (i.e.,  
250 without an exposure scenario and risk characterisation), a reference to (semi-  
251 )quantitative information demonstrating no exposure, no leaching etc. may need to be  
252 included, or a reference can be made to already existing studies with appropriate  
253 quantitative information. Measurements could be used in a qualitative assessment to  
254 show that exposure potential is not significant.

255 Several possible situations are listed in Box 1 that could lead to exposure based  
256 waiving, due to absence of exposure or exposure that is absent or not significant. A  
257 few examples are provided in Box 2 to give an indication of the potential for EBW

258 Waiving may be appropriate if the justification documents that a substance is handled  
259 in a closed system according to article 18(4), there is no consumers exposure and no  
260 dispersive use. Another example is if it can be proven (and documented with suitable  
261 evidence) that a substance is totally chemically reacted during manufacturing or if the  
262 substance is permanently bound to a matrix. Under very well documented  
263 circumstances exposure may also be considered as negligible in a specialised  
264 industrial situation with a small, well-defined and trained group of people using  
265 appropriate risk management measures to prevent exposure (with personal protective  
266 equipment used as a last resort when other strategies are not available or effective).  
267 Such measures are mentioned in the requirements for handling transported isolated  
268 intermediates (Article 18(4):

269 (a) the substance is rigorously contained by technical means during its whole lifecycle  
270 including manufacture, purification, cleaning and maintenance of equipment,  
271 sampling, analysis, loading and unloading of equipment or vessels, waste disposal or  
272 purification and storage;

273 (b) Procedural and control technologies shall be used that minimise emission and any  
274 resulting exposure;

275 (c) Only properly trained and authorised personnel handle the substance;

276 (d) In the case of cleaning and maintenance works, special procedures such as purging  
277 and washing are applied before the system is opened and entered;

278 (e) In cases of accident and where waste is generated, procedural and/or control  
279 technologies are used to minimise emissions and the resulting exposure during  
280 purification or cleaning and maintenance procedures;

281 (f) Substance-handling procedures are well documented and strictly supervised by the  
282 site operator.

283 Where measured exposure data are included, then at a minimum these need to be  
284 described by European or national standards (or referred to the source where this is  
285 documented). Further guidance on measurements on exposure is given in the chapters  
286 on exposure (Chapters R.14-17). This could include the description of the number of  
287 samples, frequency of sampling, and basic sample statistics. .

288 **Box 1. Situations that are starting points to evaluate if exposure-based waiving**  
289 **can be justified. Acceptance is based on a weight-of-evidence approach or a**  
290 **quantitative approach using exposure scenarios. Exposure levels associated with**  
291 **these situations should be low and lead to low or no significant risk.**

Specific use or limited emissions, e.g.

- Certain uses are excluded, e.g.:
  - no identified consumer uses
- Emissions to certain environmental compartments are excluded (e.g., air emissions are limited because the substance is a solid and no significant dusts or fumes are formed).
- No significant exposure, due to e.g. low emissions/ exposure to the substance, for instance due to a combination of substance properties (low vapour pressure, solids etc.) and 'no significant emissions' due to low emission rates and/or tonnage, low frequency of use etc.

Specific operational conditions or use conditions, e.g.

- Use in closed systems according to the REACH (article 18(4), leading to no significant exposure that should be argued in a quantitative way.
- Use in strictly controlled systems (according to REACH Article 18(4)) and where emission minimisation is already in place
- A substance is totally chemically reacted during manufacturing

Intensity of use (duration, frequency), e.g.

- Infrequent use due to the function of the substance leading to no significant exposure:
  - specialty products for highly specific occupational situations with a low frequency and duration, or used in closed systems, according to the REACH (article 18(4)).

No or low exposure to substances in finished articles, e.g.

- Due to physicochemical properties of the article. For instance when a substance is covalently bound to a matrix, the justification should show that there is no significant unbound residual amount, and that the covalent binding is stable (i.e., lead to no significant emissions and exposure under typical use or environmental conditions).

292

293

294 **Box 2: Examples to illustrate a) possible qualitative justifications for waiving, to**  
 295 **be justified in a weight of evidence approach in the registration dossier b)**  
 296 **possible situations where EBW is not justified**

Type of study to be waived (a)	Substance properties or operational conditions.	Argumentation
Repeated dose (dermal)	The substance is corrosive	The necessary RMM are in place due to well known corrosive effects. Dermal exposure would be not significant and e.g. repeated dose dermal toxicity studies could be waived.
Repeated dose (90 d.)	The substance is only used in closed systems, and occasional exposure is limited to maintenance or sampling tasks.  A very small, well-defined and trained group of people is exposed occasionally to low levels and using appropriate risk management measures.	The use pattern of substance is such that long-term exposure can be excluded. Expert judgement is necessary to justify the case, for instance based on evaluation of the available acute toxicity and sub-acute toxicity indicating low toxicity. Depending on tonnage, additional information based on Annex XI requirements may be more appropriate (based on an ES).
Repeated dose by inhalation.	The substance is a solid at room temperature and no or very little dust (specify) is formed for the intended uses.  The substance is a liquid with very low vapour pressure, is used in closed systems and no aerosols are formed in the process.	Due to the physicochemical properties, exposure by inhalation is absent. The formation of dusts/aerosols is not significant due to the specific operational conditions. The weight of evidence should state supporting information or measurements to underpin these assumptions.
Type of study not to be waived (b)	Substance properties or operational conditions.	Argumentation
short-term repeated dose (28 d)	Substance is used in consumer products	When a substance is used in consumer products , then relevant human exposure is difficult to exclude.
Repeated dose (90 d.)	Repeated exposure is likely but exposure levels are uncertain.	In general when repeated human exposure to a substance can be expected, waiving is not a possibility, unless it can be demonstrated in a quantitative justification that risk is negligible.

297 **R.12.4.4.1**

298 **R.12.4.4.2 Developing a weight of evidence approach**

299 A weight of evidence approach is needed to justify and document a column 2 route for  
 300 EBW. In a weight of evidence approach, relevant information on substance properties,  
 301 use and use conditions, hazard and exposure should be used to develop the case. A  
 302 general introduction on weight of evidence approaches is given in Section R.4.4.

303 Justifying exposure based waiving will generally require information that satisfies the  
304 above mentioned guiding principles (section 12.2) and is based on the main entries of  
305 the exposure scenario (Section D, Table D-2 and D-3):

- 306 1. Use description, based on the standard descriptor system
- 307 2. Processes and activities covered
- 308 3. Duration and frequency of use
- 309 4. Physical form of the substance and relevant concentration in product or article
- 310 5. Relevant operational conditions of use
- 311 6. Risk management measures
- 312 7. Waste management measures
- 313 8. Exposure information or predictions and reference to its source

314  
315 The combination of hazard profile on the one hand and the ES entries on the other  
316 hand - focusing on substance properties, operational conditions and risk management  
317 measures, type of product, throughout the life-cycle - should lead to a weight-of  
318 evidence argumentation that exposure is absent or not significant.

### 319 **Annex XI.3 - Quantitative justification for exposure-based waiving**

320 A quantitative justification can be submitted based on the Annex XI(3) requirement  
321 for exposure scenario with an accompanying exposure assessment. Even if a formal  
322 exposure assessment would normally not be required because a substance is not  
323 classified as dangerous or is a PBT/vPvB, exposure based waiving based on Annex  
324 XI(3) needs to include an exposure assessment including development of an exposure  
325 scenario. This may be appropriate when a qualitative justification of exposure based  
326 waiving is not possible due to insufficient or indecisive qualitative arguments.

327 An exposure scenario prescribes what a substance is used for, how it is used and  
328 under which operational conditions, and what risk management measures are taken to  
329 control the exposure of man and the environment. Sections D.1 to D.3 detail how an  
330 exposure scenario is built and how it is used for the exposure assessment.

331 The quantitative exposure estimate relevant to the test that is waived will be compared  
332 to any derived threshold effect level (PNEC or DNEL, based on the information that  
333 *is* already available) relevant for the specific test being waved. If a no-effect level or  
334 minimal effect level cannot be derived (e.g. due to the lack of relevant hazard  
335 information for the endpoint), it may be possible to use an appropriate, accepted  
336 threshold of toxicological concern (TTC). TTCs have so far only been used in Europe  
337 a regulatory context for food contact materials and flavourings. The use of TTCs is  
338 discussed elsewhere in the hazard guidance (cross ref to RIP 3.3 part 4, section 8.1,  
339 Appendix on TTC). In cases where no reliable or suitable PNEC, DNEL, DMEL or  
340 TTC is available, it will be very difficult to argue on quantitative grounds that further  
341 testing for a specific endpoint is not needed. Additional hazard data may need to be  
342 collected instead of waiving the test, or a qualitative justification for EBW might still  
343 be possible.

344 Several occupational cut-off values have been proposed for gases and fumes, dust  
345 particles and substance properties leading to no significant exposure. For substances  
346 in consumer products, cut-off values for oral, dermal and inhalation uptake have been  
347 proposed as well (Bunke et al., 2006). For the environment, aquatic threshold levels

348 have also been derived. If agreed cut-off values are available for a certain substance of  
349 group of substances below which the likelihood that adverse effects occur are  
350 negligible, the EBW justification should demonstrate that the exposure levels actually  
351 conform to these cut-off values. Additional scientific and regulatory discussions on  
352 these cut-off values is needed before integration into the guidance can take place.

353 If a DMEL/DNEL or PNEC or an agreed TTC or agreed cut-off level is available, the  
354 exposure assessment will continue with a risk characterization to demonstrate that  
355 risks are controlled and waiving is appropriate (Section E.1).

## 356 **DOCUMENT EXPOSURE BASED WAIVING**

357 If waiving is applied, the hazard and exposure considerations, including the  
358 interaction between them should be documented, based on a qualitative or semi-  
359 quantitative justification, or a quantitative justification based on exposure scenarios.

### 360 **Qualitative justification based on Column 2 adaptations**

361 If a qualitative or semi-quantitative justification was used, the weight of evidence  
362 justification should be given under the appropriate headings in the registration dossier  
363 referring to the appropriate specific rule(s) in column 2 or in Annex XI.

364 It could be considered to use the exposure scenario format to document a qualitative  
365 assessment (Section D, Table D1-2) since the information that is needed for justifying  
366 a qualitative waiving should be related to the regular entries into an exposure  
367 scenario. In any case, the entries into the exposure scenario reflect the principal  
368 information needs into the weight of evidence approach, that can be adapted if they  
369 are not needed to justify waiving.

### 370 **Quantitative justification based on Annex XI(3).**

371 If the waiving is supported by an exposure assessment including development of  
372 exposure scenarios, this shall be documented in the Chemical Safety Report.

373 The exposure assessment relevant to the waiving justification can be reported under  
374 the relevant exposure scenario as shown in the format for the CSR (REACH Annex  
375 1). Further guidance on making the CSR is given in Part F.

376 According to REACH Annex 1, an exposure assessment and exposure scenarios are  
377 not required in the chemical safety assessment if the substance is not classified  
378 dangerous or not PBT/vPvB. Nevertheless, it is considered appropriate to document  
379 the quantitative waiving justification in the exposure assessment section of the CSR.

## 380 **COMMUNICATE CONDITIONS OF USE THROUGH THE SUPPLY CHAIN**

381 The last step after finishing the EBW justification is to communicate the conditions of  
382 use which apply to the identified uses for a specific EBW case. Especially if  
383 operational conditions of use or risk management measures are essential for achieving  
384 no or no significant exposure, these must be communicated downstream as  
385 prerequisites for the relevant identified use(s). The operational conditions and RMMs  
386 as specified in the weight-of evidence documentation or the ES must be

387 communicated through the chemical supply chain via the SDS or otherwise if an SDS  
388 is not required (REACH article 32).

#### 389 **UPDATING THE WAIVING DOCUMENTATION**

390 New information after registration may trigger the obligation to update the exposure  
391 scenarios, the CSA and the CSR. Then the registration also needs to be updated. If  
392 either the hazard information or the conditions of use need to be changed in the  
393 registration update, the validity of the waiving argumentation needs to be re-  
394 evaluated.

395 In case the new information relates to additional hazard information, the waiving  
396 argumentation may need to be re-evaluated to decide if the weight of evidence  
397 argumentation is still valid.

398 If new information relates to new identified uses that are promoted by the substance  
399 manufacturer/importer, the waiving argumentation should ascertain if the exposure  
400 assessment (whether qualitative or quantitative-based on exposure scenarios) is still  
401 valid.

402

403

### **REFERENCES**

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