

TECHNICAL GUIDANCE DOCUMENT FOR PREPARING THE CHEMICAL SAFETY ASSESSMENT

Part F: Guidance on preparing the CSR

**“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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Convention for citing the current REACH regulation

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

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1 **F.1 INTRODUCTION**

2 **F.1.1 Goals of the CSR**

3 The main goal of the chemical safety report (CSR) is to document all stages of the chemical safety
4 assessment (CSA), including its conclusions and results, with regard to the standard elements of the
5 CSA as explained in part A of the technical guidance document. This guidance is meant to assist the
6 registrant to write a chemical safety report that documents the chemical safety assessment as laid
7 out in Parts A to E of the technical guidance document. The chemical safety assessment needs to be
8 conducted according to the EU REACH legislation (Regulation (EC) No 1907/2006). The elements
9 to be included in the report are listed in the format provided in Annex I, point 7 of the Regulation.

10 The REACH registration technical dossier and the CSR present the key information on a substance
11 that is needed to comply with registration requirements. The CSR will also be the scientific basis
12 for subsequent activities by the European Chemicals Agency or member states. This guidance
13 briefly describes the content of each section. The development of this TGD was accompanied by an
14 exemplification process where M/I and DU companies cooperated to apply the guidance under real
15 life conditions. This has delivered chemical safety report examples to illustrate the work processes
16 defined in Chapters A-G of this guidance. The examples will be made available for public access on
17 the Cefic web site, and a process will be started together with the European Chemicals Agency to
18 ensure that the examples are appropriate to accompany the guideline. Additional examples (e.g. on
19 exposure-based waiving) can be added to this depository once these become available.

20 The report should be stand-alone, readily understandable and the principles applied, assumptions
21 made and the conclusions drawn should be transparent. The key data should be easily identifiable
22 without the need to revert to the underlying data sets (i.e., the IUCLID data set). Only relevant
23 information for the chemical safety assessment is presented, indicating that only a part of the
24 information in IUCLID is repeated. The template for the chemical safety report will be available
25 from the ECHA website (http://ec.europa.eu/echa/reach_en.html)¹.

26 **F.1.2 Data transfer to and from the CSR**

27 It is foreseen that IT tools will become available to assist in generating the CSR with input from
28 IUCLID 5 and suitable Tier 1 assessment tools (see Section D.4). Generally the information in
29 IUCLID 5 for specific endpoint studies will be more detailed than required for the CSR and a
30 mechanism is needed to transfer the endpoint summary information in IUCLID into the CSR.

31 The output of suitable Tier 1 tools is currently not structured according to the needs for REACH. In
32 future, these tools will need a function to structure the output of the exposure assessment into the
33 relevant sections of the CSR.

34 The content of the CSR, especially the information in the exposures scenario(s), will need to be
35 transferred to the SDS (see part G). This encompasses both transfer from the core information in the
36 CSR and the CSR into the SDS, but it could also entail translation of the exposure scenario into
37 content that is suitable for the purpose of the SDS and the needs of the DU.

1 At the time of writing this guidance, this template was not yet available.

38 These issues are complicated and results from several REACH implementation projects are needed
39 to achieve these goals, e.g. the RIP3.1 project, the RIP IT Tools project etc.

40 **F.2 WRITING THE CHEMICAL SAFETY REPORT**

41 **F.2.1 General requirements**

42 The CSR should enable all users to understand the chemical safety assessment and the scientific
43 arguments that support the conclusions of the hazard assessment, and, if the substance meets the
44 criteria for classification as dangerous or is considered to be a PBT/vPvB, exposure assessment
45 and risk characterisation. It is emphasised that key information in the CSR on hazard and exposure
46 must be clearly presented and justified, must be traceable to its sources and documented properly
47 with regard to equations, units, references and calculation or IT-tools used.

48 The CSR should be consistent on the assumptions with regard to hazard, exposure estimation and
49 the recommendations in the exposure scenario. The assumptions on operational conditions and risk
50 management must be traceable in the exposure estimation and consistent with the final exposure
51 scenario in the CSR. This is needed to evaluate whether the exposure scenario, if present, is based
52 on the conclusions of a chemical safety assessment and the recommended risk management
53 measures are valid to ensure control or risks. Therefore, the CSR should clearly present the key
54 studies or information for each section, document the key assumptions and provide an interpretation
55 and conclusion narrative for each section.

56 Key information that is present elsewhere (e.g., in the IUCLID database) should be presented in a
57 brief table format and referenced, rather than repeat the details. A narrative interpretation and
58 conclusion section is usually needed. When there are multiple sources of key data for hazard or
59 exposure, the choice of the key information needs to be justified. This justification can be reported
60 in the endpoint summaries in the IUCLID 5 dossier and included in the CSR.

61 REACH requires that the CSR follows a certain format according to Annex 1 and lays down the
62 headings of the sections. Each section as listed in Annex I of REACH needs to contain

- 63 i. A report of results from the CSA. If results were derived by means of quantitative methods,
64 details should be presented to allow an evaluator to reproduce the results. If results were
65 derived by means of a qualitative (weight of evidence) reasoning, this should be reported.
- 66 ii. For any endpoint in the hazard or PBT/vPvB sections for which no relevant information is
67 available, the relevant section shall contain the sentence: 'This information is not available'.
68 In addition, a statement could be added if the information is not required for a tonnage band or
69 that the results of the CSA do not indicate that it should be taken into account (e.g., when the
70 CSA does not indicate an exposure-triggered risk to soil organisms as in REACH Annex X-
71 9.4).
- 72 iii. A statement that although the hazard information is or could be required, the information can
73 be waived. This needs to be argued and documented in a weight-of-evidence or quantitative
74 reasoning, but the data waiver is included in IUCLID 5 (see Chapter R.2).
- 75 iv. The reason why information on specific exposure pathways is not reported. This should be
76 clearly stated and argued. The absence of exposure information should be clear in order to
77 evaluate if exposure based triggers have been correctly considered.

- 78 The information of each section of the CSR usually contain both
- 79 i. Factual information on hazard or exposure. Where possible, overview information should be
80 presented in a table format, presenting the relevant information and identify the key
81 information or study.
- 82 ii. A narrative and an interpretation of results for the chemical safety assessment.

83 **F.2.2 Part A**

84 **F.2.2.1 A summary of the risk management measures.**

85 The goal of section (A.1) is to present a compact overview of the relevant risk management
86 measures for the identified use(s), based on the exposure scenario(s) that are in the CSR. A straight
87 forward way to structure this section is to list each of the recommended RMMs by the different
88 protection targets:

- 89 • protection of human health hazard due to physico-chemical properties of the substance
90 • controlling emission to, and exposure of, workers
91 • controlling emission to, and exposure of, consumers
92 • controlling emissions to, and exposure of, the environment
93

94 RMM should be stated in a way which makes clear to downstream users what is expected of them.
95 Where standard RMM phrases are used, e.g. from the RMM library, the codes should be
96 accompanied by the RMM in plain words.

97 **F.2.2.2 Declaration that risk management measures are implemented**

98 Part A.2 of the chemical safety report includes a declaration that the risk management measures in
99 the relevant exposure scenarios for the registrant's own manufacturing and use(s) are implemented
100 by him. If applicable, a statement that the facility operates under a certified quality control system
101 can be added.

102 **F.2.2.3 Declaration that risk management measures are communicated**

103 This part declares that the RMMs for the identified uses are communicated to down stream users
104 (formulators and other downstream users) by means of the safety data sheet(s).

105 **F.2.3 Part B**

106 **Part B** of the CSR documents the different parts of the chemical safety assessment. For any missing
107 information, the reason why information is missing should be stated or justified according to the
108 general requirements of Section F.2.1.

109 **F.2.3.1 Identity of the substance and physical and chemical properties**

110 **F.2.3.1.1 Identity of the substance**

111 Detailed guidance on substance identity is available at the internet pages of the European Chemicals
 112 Agency (http://ec.europa.eu/echa/reach_en.html). This section presents a brief overview of the
 113 information that is required in this section (cf. REACH Annex VI(2)). It should be clear to which
 114 form or forms of substance the registration and the presented information relate. If it is not
 115 technically possible or if it does not appear scientifically necessary to give information on one or
 116 more of the items below, the reasons shall be clearly stated. Attention should be paid, if applicable
 117 and appropriate, to specific additional substance properties, e.g., information on optical activity and
 118 typical ratio of (stereo) isomers.

119 For a single substance, the composition is reported as degree of purity, known impurities or
 120 additives, difference of impurities among products. For mixtures, the composition is reported as
 121 percentages or range of percentages of mixture descriptors, known impurities or additives,
 122 differences among products.

123 The following basic information is required (REACH Annex VI), e.g. in a table format:

- 124 • Name or other identifier of each substance; Name(s) in the IUPAC nomenclature or other
 125 international chemical name(s); Other names (usual name, trade name, abbreviation);
 126 EINECS or ELINCS number (if available and appropriate); CAS name and CAS number (if
 127 available); Other identity code (if available)
- 128 • Information related to molecular and structural formula of each substance; Molecular and
 129 structural formula (including SMILES notation, if available); Information on optical activity
 130 and typical ratio of (stereo) isomers (if applicable and appropriate); Molecular weight or
 131 molecular weight range

Name:

EC Number: [.....]
 CAS Number: [.....]
 IUPAC Name: [.....]
 Molecular Formula: [.....]
 Structural Formula: [.....]
 Molecular Weight: [.....]
 Synonyms: [.....]

132

- 133 • Composition of each substance; Degree of purity (%); Nature of impurities, including
 134 isomers and by-products; Percentage of (significant) main impurities; Nature and order of
 135 magnitude (... ppm, ... %) of any additives (e.g. stabilising agents or inhibitors);

- 136 • Additional substance properties are available via the technical dossier.

Purity: [.....]
 Impurities: [.....]
 Additives: [.....]

137

138 **F.2.3.1.2 Physical and chemical properties**

139 Basic physical-chemical properties (if applicable) and a reference to their source needs to be
140 included, as discussed in part B.

141 At REACH Annex VII levels (substances produced or imported at ≥ 1 t/a) these properties need to
142 be reported: Physical state at 20° C and 101.3 KPa, melting point/freezing point, boiling point,
143 Relative density, Vapour pressure, Surface tension, Water solubility, Partition coefficient n-
144 octanol/water (log Kow), Flash point, Flammability, Explosive properties, Self-ignition
145 temperature, Oxidising properties, Granulometry.

146 In addition, at REACH Annex IX levels (substances produced or imported ≥ 100 t/a), the following
147 properties need to be reported as well (if relevant): Stability in organic solvents and identity of
148 relevant degradation products (not for inorganic substances), Dissociation constant and viscosity.

REACH ref Annex, §	Property	Value(s) Indicate key study if needed	Reference for key study
VII, 7.1	Physical state at 20 C and 101.3 KPa		
VII, 7.2	Melting point		
VII, 7.3	Boiling point		
VII, 7.4	Relative density		
VII, 7.5	Vapour pressure		
VII, 7.6	Surface tension		
VII, 7.7	Water solubility		
VII, 7.8	Partition coefficient n-octanol/water (log value)		
VII, 7.9	Flash point		
VII, 7.10	Flammability		
VII, 7.11	Explosive properties		
VII, 7.12	Self-ignition temperature		
VII, 7.13	Oxidising properties		
VII, 7.14	Granulometry		
IX, 7.15	Stability in organic solvents and identity of relevant degradation products		
IX, 7.16	Dissociation constant		
IX, 7.17	Viscosity		

149 **F.2.3.2 Manufacture and uses**

150 The goal of this section is to document an overview on manufacture and uses. It should also report
151 the tonnage band of the substance(s) in the registration.

152 This section is also meant to demonstrate grouping of similar uses that lead to comparable exposure
153 patterns and RMMs, covered by broad exposure scenarios (also called '*use-and exposure*
154 *categories*' (Article 10).

155 F.2.3.2.1 Information on manufacture

156 This section should present information on manufacture, and is based on the technical dossier,
157 Annex VI(3). It also provides the basis for the second entry into the exposure scenario (Table
158 D1-2, 2nd entry). The harmonised descriptor system of Section D.3.3 can be used to describe the
159 industry sector where manufacture takes place (Appendix D-1, pick list for sector of use). The
160 activities during manufacture that are relevant can be described by process categories reflecting the
161 exposure potential (Appendix D-2, pick list for process categories / operation units).

162 F.2.3.2.2 Identified uses

163 This section should list all identified uses of the substance to be registered. Identified uses are uses
164 that the registrant is willing and able to support through an appropriate ES documented in the CSR,
165 and communicated to the DU in the SDS. This section can be completed in different ways, to allow
166 for a structured analysis of identified use and to allow grouping of similar uses into broad exposure
167 scenarios.

- 168 • Present simply a *list* of all the registrant's identified uses by using the harmonised descriptor
169 system. The terminology of the descriptor system provides a common point of reference.
170 However, not all four descriptors need to be used. The descriptor system can be used at
171 higher aggregation levels, or only partially, if that is considered sufficient to describe the
172 identified uses.
- 173 • Present *an analysis* of all the registrant's identified uses based on the descriptor system, for
174 instance if the registrant wants to provide a structured overview of the identified uses, or e.g.
175 argue grouping of similar uses. A suggested structure for such an analysis is i) an
176 introduction to the rationale ii) a (tabulated) overview of the major and minor industry
177 sectors of use with their respective descriptor iii) for each sector of use, a matrix indicating
178 combinations of the sector, the technical function and the end-use preparations or articles
179 and iv) an overview matrix of identified uses.

180 F.2.3.2.3 Uses advised against

181 The uses advised against shall be justified and recorded in the CSR (and communicated via Section
182 16 of the SDS). This can be an initiative of the M/I or a reaction to uses made known to him. Any
183 downstream user has the right to make a use known to the manufacturer, importer, downstream user
184 or distributor who supplies him with a substance on its own or in a preparation with the aim of
185 making this an identified use. However, the manufacturer can advise against certain uses for reasons
186 of protection of human health or the environment. For such uses, a downstream user still has the
187 option to prepare his own CSR.

188 **F.3 CLASSIFICATION AND LABELLING**

189 C&L should be summarised in section 3. The appropriate classification and labelling developed in
190 accordance with the criteria in Directive 67/548/EEC shall be presented and justified. Where
191 applicable specific concentration limits, resulting from the application of Article 4(4) of Directive
192 67/548/EEC and Articles 4 to 7 of Directive 1999/45/EC, shall be presented and, if they are not
193 included in Annex I to Directive 67/548/EEC, justified.

194 If the information is inadequate to decide whether a substance should be classified for a particular
195 end-point, the registrant shall indicate and justify the action or decision he has taken as a result. He
196 should also indicate for each endpoint for which no classification is proposed whether this is based
197 on conclusive data, inconclusive data or lack of data.

198 Guidance on this is given for each specific endpoint in the hazard guidance (Chapter R.7).

199 Classification and Labelling information in the CSR should be consistent with the labelling and the
200 SDS for the substance.

201 Classification

202 Substance *Q* is classified [if applicable] for physical - chemical properties [mention relevant
203 classification], for health effects [mention relevant classification], or for environment
204 (mention relevant classification). A structured overview is presented below.

- 205 • R phrases
- 206 • S phrases
- 207 • Specific concentrations limits

208 **F.4 ENVIRONMENTAL FATE PROPERTIES**

209 Whenever tests are referred to, the type of test should be described including the Test Guideline
210 applied.

211 **F.4.1.1 Degradation**

212 **F.4.1.1.1 Abiotic degradation**

213 Report on hydrolysis, photodegradation, or oxidation processes and rates for water and air. Report
214 how the information was obtained (test results or estimated) including a reference to the source or
215 model, and report the degradation rates and calculated half-lives.

216 Interpret the findings and conclude with regard to stability in water, air and soil or sediment.

217 **F.4.1.2 Biotic degradation**

218 Report on biotic degradation by mentioning the type of test(s) employed and the result of the test.
219 Present additional information if you report on multi-constituent substances, UVCBs etc. Justify the
220 applicability of the data.

221 Interpret the findings and conclude with regard to stability in water, and soil or sediment.

222 **F.4.1.3 Environmental distribution**

223 Report the results of the available sorption studies (water-solids). Discuss the partitioning in the
224 light of substance properties, including partitioning coefficients.

225 Describe how the distribution was calculated (see Chapter R.16). Report on the preference for
226 partitioning to soil/sediment, air and water and present information on the mass distribution over the
227 various compartments, preferably in a table format.

228 Interpret the findings and conclude with regard to the distribution of the substance after emissions,
229 e.g. transport to (ground) water (leaching), air or soil/sediment.

230 **F.4.1.4 Bioaccumulation**

231 Report when available bioconcentration factor (BCF) for fish and/or invertebrates and how it was
232 measured or estimated.

233 Report conclusions on the bioaccumulation potential of the substance based on measured or
234 estimated BCF or $\log K_{ow}$.

235 **F.4.1.5 Secondary poisoning**

236 Report the bioaccumulation and biomagnification factors for the selected food chain and how they
237 were measured or estimated (see Chapter R.16.). Interpret the findings with regard to the potential
238 to bio-accumulate in the food chain.

239 **F.5 HUMAN HEALTH HAZARD ASSESSMENT**

240 This section reports the outcome of the human health hazard assessment as explained for each
241 endpoint in part B of the TGD.

242 Report the results for each endpoint in a short narrative that identifies the type of adverse effects
243 and conclusive statements that support the results. An overview of relevant results can be presented
244 in as summary table, indicating the type of study, the toxicological endpoint found, and a reference
245 to its source (IUCLID 5 endpoint summaries). The key study for a specific endpoint should be
246 indicated. Interpret the findings with regard to DNEL derivation, classification and labelling and the
247 PBT assessment (if applicable). Whenever tests are referred to, the type of test should be described
248 including the test guideline applied. In case testing proposals have been made to the Agency, this
249 should be mentioned for the relevant endpoint.

250 **F.5.1 Toxicokinetics (absorption, metabolism, distribution and elimination)**

251 Information available on the toxicokinetic profile (i.e. absorption, metabolism, distribution and
252 elimination) should be summarised (in a table format if appropriate) and the impact on specific
253 endpoints should be described here. Key studies should be flagged.

-
- 254 **F.5.2 Acute toxicity**
- 255 **F.5.3 Irritation**
- 256 **F.5.3.1 Skin**
- 257 **F.5.3.2 Eye**
- 258 **F.5.3.3 Respiratory tract**
- 259 **F.5.4 Corrosivity**
- 260 **F.5.5 Sensitisation**
- 261 **F.5.5.1 Skin**
- 262 **F.5.5.2 Respiratory system**
- 263 **F.5.6 Repeated dose toxicity**
- 264 **F.5.7 Mutagenicity**
- 265 **F.5.8 Carcinogenicity**
- 266 **F.5.9 Toxicity for reproduction**
- 267 **F.5.9.1 Effects on fertility**
- 268 **F.5.9.2 Developmental toxicity**
- 269 **F.5.10 Other effects**
- 270 Present a summary of results for each endpoint to humans under the relevant heading. Relevant
271 (test) results and test conditions should be reported with a reference to their source (preferably in a

272 table format). It is recommended to separate animal data, human data and other data/information by
 273 subheadings. Justify missing data, e.g., by referring to the lack of legal testing requirements

274 For each endpoint, address the dose-response relationship and the relevant N(L)OAEL. Interpret the
 275 findings in terms of relevance for derivation of the DNEL and classification and labelling. In order
 276 to select the leading DNEL in the next CSR chapter, end-point specific DNELs need to be set (if
 277 applicable). Endpoint-specific DNELs are needed to derive only one DNEL per target group and
 278 exposure route and duration.

Study type	Study results	Remarks	Reference
[Name]	[Duration] [N(L)OAEL]	[Reliability]	[author] [year]

279 **F.5.11 Derivation of DNEL(s)**

280 This section reports how the DNEL for the leading health effect is derived. This should follow from
 281 a summary of the health effects and end-point specific DNELs, and the derived DNELs for each
 282 relevant exposure pattern (duration, frequency, route and exposed human population) that result
 283 from the identified uses in the exposure scenario. A table format for such an overview is presented
 284 in Section R.8, Appendix 1. The assessment factors that are used need to be justified in this section
 285 based on the guidance in Section B.8.1 and Chapter R.8.

286 In those cases where a DNEL cannot be derived, the reason for this shall be clearly stated and
 287 justified, e.g.

288 [The available data do not allow to reliably identify the threshold]

289 [A substance exerts its effect by a non-threshold mode of action]

290 [Test data or other relevant information are absent]

291 Specifically for non-threshold mutagens/carcinogens, a DMEL (derived minimal effect level) may
 292 be derived if the available data are judged of sufficient quality. Report the derivation of the DMEL
 293 in the required detail according to Section R.8.9).

294 **F.6 HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICOCHEMICAL** 295 **PROPERTIES**

296 **F.6.1 Explosivity**

297 **F.6.2 Flammability**

298 **F.6.3 Oxidising potential**

299 Report the relevant test result for each property under the appropriate heading. Whenever tests are
 300 referred to, the type of test should be described including the test guideline applied. Interpret the
 301 findings with regard to classification and labelling.

302 **F.7 ENVIRONMENTAL HAZARD ASSESSMENT**

303 **F.7.1 Aquatic compartment (including sediment)**

304 *Note: The following text also applies to sections 7.2, 7.3 and 7.4.*

305 Report the results of the hazard assessment (cf. Part B) for each environmental sphere in a short
306 narrative that identifies the type of adverse effects, the critical taxonomical group and conclusive
307 statements that support the results.

308 Whenever tests are referred to, the type of test should be described including the test guideline
309 applied. In case testing proposals have been made to the Agency, this should be mentioned for the
310 relevant endpoint.

311 An overview of relevant results can be presented in as summary table (IUCLID endpoint
312 summaries), indicating for each relevant study the type of organism, the toxicological endpoint
313 tested, and a reference to its source. It is recommended to separate taxa by subheadings.

Organism	Study results	Remarks	Reference
[test species]	[Duration] [LC50]	[Reliability]	[author] [year]

314 Indicate the key study for deriving the PNEC, as well as the reasoning for selecting this study as
315 key study, and interpret the findings (preferably under separate subheadings) with regard to PNEC
316 derivation, classification and labelling and the PBT assessment (only for the aquatic compartment).

317 Present the derivation of the PNEC for each relevant compartment, and provide justification for the
318 value of the assessment factor that is applied to the key study or studies (in case both chronic and
319 acute data are available). Specific guidance is given in Section B.8.2 and Chapter R.10.

320 **F.7.2 Terrestrial compartment**

321 [idem]

322 **F.7.3 Atmospheric compartment**

323 [idem]

324 **F.7.4 Microbiological activity in sewage treatment systems**

325 [idem]

326 tasks

327 **F.8 PBT AND VPvB ASSESSMENT**

328 This section reports the outcome of the PBT and vPvB assessment, as explained in part C. Present
 329 the outcome of the screening assessment if this has been done. If better information is available on
 330 which a definitive assessment can be made, present these data in the PBT assessment.

331 For each PBT or vPvB property, a comparison with the screening criteria is needed and a
 332 conclusion drawn for each property (See Part C and Chapter R.11)

Type of data for [P, B or T]	Criterion	Screening assignment
[Type of test] [Result]	[PBT/vPvBcriterion]	[yes/no] [P,B,T] [vP vB]

333 Present the final conclusion based on the evaluation of all screening criteria for P, B and T in
 334 conjunction. This could be supported by a table summary of the relevant information, for each
 335 property. If the substance is concluded to be a potential PBT, vPvB, present the results of the
 336 additional testing or additional information that was collected. Interpret the results and conclude on
 337 whether the substance should be treated as a PBT/vPvB substance. If this is the case, additional
 338 reporting is needed in sections 9 and 10 of the CSR.

339 **F.9 EXPOSURE ASSESSMENT**

340 **F.9.1 Title of first exposure scenario**

341 **F.9.1.1 Exposure scenario**

342 Each exposure scenario is listed, conforming to the core content of an exposure scenario (see Part
 343 D). The exposure scenario in the CSR may be different in content and language than the ES that is
 344 communicated to the downstream user via the SDS. The ES in the CSR contains more detailed
 345 information than the ES in the SDS.

346 **F.9.1.2 Exposure estimation**

347 The section is structured by reporting each exposure scenario that was developed, followed by the
 348 corresponding exposure estimation. Start each subsection with the short title of the ES.

349 The next subheading requires description of the exposure estimation. Although not explicitly stated,
 350 it is recommended to use the subheadings of section 10 of REACH Annex 1 to systematically run
 351 through each ES.

- 352 • Human health
 - 353 ○ Workers
 - 354 ○ Consumers
 - 355 ○ Indirect exposure to humans via the environment
- 356 • Environment
 - 357 ○ Aquatic compartment (including sediment)

- 358 ○ Terrestrial compartment
- 359 ○ Atmospheric compartment
- 360 ○ Microbiological activity in sewage treatment systems
- 361

362 The following basic elements are part of the exposure estimation for each exposure scenario:

- 363 • Document how exposure has been estimated, incl. whether measurements and/or tools have
364 been applied. Report (summaries of) relevant measured data.
- 365 • In case standard tools have been applied, indicate clearly which determinants and values have
366 been used for the estimation (see chapter D.4). Export files of standard exposure tools can be
367 annexed to the CSR. The information given shall enable the reader to repeat any
368 calculation/estimation.
- 369 • In case non-standard tools have been used, these need to be carefully introduced.
- 370 • If quantitative exposure estimates cannot be derived, provide a qualitative evaluation of
371 exposure, e.g. when a case has been made for exposure-based waving due to absence of
372 exposure or exposure that is not significant.
- 373

374 If the information is not available, waived or found to be not relevant due to negligible risk,
375 document for each target group and exposure pathway the reasons for not considering it or give a
376 weight-of evidence narrative if appropriate.

377 Human health

378 The exposure estimate should be related to the conditions of use in the ES, e.g. duration and
379 frequency, relevant stage of the life cycle, source of exposure, RMMs. Document where exposure is
380 not expected to occur. The resulting exposure levels should be stated at the end of each section.

381 The outcome of the environmental exposure assessment is needed to calculate human intake via the
382 environment. Report the overall exposure via the environment.

383 Document the outcome of the combined exposure calculations via all pathways for the different
384 populations separately, and combined (i.e., cumulative for workplace, exposure from consumer
385 products and via the environment). If such combinations are considered unrealistic, justify the
386 relevant combinations of exposure.

387 Environment

388 The exposure estimate should be related to the conditions of use described in the ES, e.g., emission
389 reduction measures, emissions in relevant stages of the life cycle, frequency and pattern of
390 exposure, RMMs. Document where exposure is not expected to occur based on relevant
391 information. The resulting predicted environmental exposure concentrations (PECs) should be
392 stated at the end of each section.

393

394 **9. n. Title of first exposure scenario *n*.**

395 Repeat exposure scenario and exposure estimation for exposure scenario *n*.

396

397 **F.10 RISK CHARACTERISATION**

398 Report the outcome of the risk characterisation for the target groups and exposure pathways
399 mentioned in Annex I (7) of REACH, and for each exposure scenario that was developed in the
400 CSA. A quantitative risk characterisation is required for substances for which DNELs or PNECs
401 can be derived. A qualitative risk characterisation should be reported for substances for which no
402 thresholds can be derived ((see Part E). Discuss the outcome of the risk characterisation due to the
403 uncertainties in hazard and exposure estimation. If applicable, report the results of an uncertainty
404 analysis (see Chapter R.19).

405 **F.10.1 Title of first exposure scenario**

406 **F.10.1.1 Human health**

407 **F.10.1.1.1 Workers**

408 **F.10.1.1.2 Consumers**

409 **F.10.1.1.3 Indirect exposure to humans via the environment**

410 Systematically go through the risk characterization ratios (Exposure / DNEL) for each population
411 and exposure pathways relevant to the ES, and report the risk characterization ratios for these
412 pathways or the relevant combined pathways.

413 For those human effects and those environmental spheres for which it was not possible to determine
414 a DNEL or a PNEC, a risk characterization ratio cannot be derived. In those cases, a qualitative
415 assessment of the likelihood that effects are avoided when implementing the exposure scenario shall
416 be carried out. A qualitative comparison of information on hazard and effects with exposure data
417 should be made and interpreted.

418 **F.10.1.2 Environment**

419 **F.10.1.2.1 Aquatic compartment (including sediment)**

420 **F.10.1.2.2 Terrestrial compartment**

421 **F.10.1.2.3 Atmospheric compartment**

422 **F.10.1.2.4 Microbiological activity in sewage treatment systems**

423 Systematically go through the risk characterization ratios (PEC / PNEC) for each population and
424 exposure pathways relevant to the ES, and report the risk characterization ratios for these pathways
425 or the relevant combined pathways.

426 If it is not possible to derive a risk characterization ratio, a qualitative comparison of effects with
427 exposure data should be made.

428

429 **10. n. Exposure scenario *n*.**

430 Repeat the risk characterization for exposure scenario *n*.

431 **10.(n+1) Combined exposure from different sources**

432 This section should present an evaluation of the risks due to combined exposure from the uses
433 covered by different exposure scenarios. It is possible that uses of the same substance described in
434 different ESs can lead to combined exposure, e.g. different consumer uses combined with exposure
435 via the environment. In such cases the overall risk needs to be evaluated and presented here.

436 **REFERENCES**

437 Although not required in the CSR format of Annex 1, it may be recommended to list all references
438 at the back of the document.

439 **APPENDICES**

440 Although not required in the CSR format of Annex 1, it can be recommended to annex a formatted
441 output of models that were used to derive physical-chemical properties, environmental fate
442 properties or human or environmental exposure. Refrain from attaching all model results in the
443 annex without a proper interpretation in the body of the CSR.