



TECHNICAL GUIDANCE DOCUMENT FOR PREPARING THE CHEMICAL SAFETY ASSESSMENT

Part E: Risk Characterisation

**“Technical Guidance Documents in support of the New EU Chemicals Legislation (REACH) –
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1 **E.1 INTRODUCTION**

2 **E.1.1 Aim**

3 In risk characterisation, exposure levels are compared to suitable predicted or derived no-effect
4 levels to yield so-called Risk Characterisation Ratios (RCRs) for each protection goal to decide if
5 risks are controlled.

6 **E.1.2 Background**

7 Risk Characterisation Ratios (RCRs) are derived for all end-points and time scales, environmental
8 and human. RCRs are derived by comparing exposure levels to suitable predicted or derived (no)-
9 effect levels. For the environmental end-points, this is the ratio of PEC to PNEC. For the human
10 end-points a distinction need to be made between threshold and non-threshold substances. For
11 threshold substances the RCR is the ratio of the estimated exposure and the DNEL. Risk
12 characterisation of non-threshold substances entails a comparison between the estimated exposure
13 and the DMEL.

$$RCR = \frac{PEC}{PNEC} \text{ or } \frac{Exposure}{DNEL} \text{ or } \frac{Exposure}{DMEL}$$

Equation E-1

14 Control of risk for the substances is demonstrated when RCRs for all identified uses, all end-points
15 and all exposed populations are below one, and the outcome of both the hazard assessment and the
16 exposure assessment are robust.

17 The above does not include the assessment of the physicochemical risk to human health. Such an
18 assessment must be carried out for substances which have been classified on the basis of certain
19 physicochemical properties (explosivity, flammability or oxidising potential), or if there are other
20 reasonable grounds for concern.

21 **Assessment steps**

Step 0 If the substance is classified for physical danger (see Chapter R.9), carry out a risk
characterisation for physicochemical risk (See Chapter E.2).

Step 1 Collect the no-effect levels or minimal effect levels (PNECs, DNELs or DMELs if
appropriate) for the relevant time scales, environmental ecosystems, human populations,
endpoints of concern, and routes of exposure. For the derivation of these data see
Chapter R.8 and R.10.

Step 2 For each exposure scenario collect the exposure values, measured or estimated, for the
relevant time scales and spatial scales, environmental compartments, human populations
and human routes of exposure. For a definition of short term (acute exposure) and long
term (chronic exposure), please refer to the relevant hazard chapters (Chapter R.8) and
the exposure assessment chapters (Chapters R.14-16).

Step 3 Calculate the ratio of matching exposure and no-effect levels for all relevant matching
combinations. This is described in Chapter E.3 (humans) and E.4 (environment).

Step 4 Calculate the sum of combined exposure for each human population and for the general

population (combined worker and consumer exposure).

Step 5 Decide on possible iterations of the CSA, taking uncertainties in the assessment into account (see Chapter R.19). The risk characterisation should demonstrate control of risks, based on a sufficiently robust hazard and exposure assessment.

Step 6 Finalise the risk characterisation.

22 **E.1.3 Principles**

23 Risk characterisation in the context of the CSA is the (quantitative) estimation of the likelihood that
24 adverse effects occur to man or the environment due to actual or predicted exposure to a toxic
25 chemical (Van Leeuwen, 1995). The risk characterization ratio (RCR) is often used as a measure of
26 the risk. Safe use of substances is demonstrated when RCRs are below one. If the RCR shows that,
27 based on the tentative ES, risks are not adequately controlled, further work would be needed. In a
28 second iteration of the CSA, information at any point of the assessment cycle can be modified. The
29 CSA process can be refined in a number of iterations. Such iterations must be realistic to the extent
30 that the introduction of activities and/or RMMs that cannot be implemented in practice should be
31 avoided.

32 In order to produce a meaningful risk characterisation it is important that the assessor both
33 understands, and takes into account the uncertainties associated with the information/data that is
34 provided. Uncertainties related to both the hazard assessment and the exposure assessment should
35 be addressed in the CSA (see Step 5). Methods for uncertainty analysis can be found in Chapter
36 R.19.

37 **E.2 RISK CHARACTERISATION FOR PHYSICO-CHEMICAL PROPERTIES**

38 **E.2.1 General aspects**

39 Substances which are dangerous because of their physicochemical hazard trigger the additional
40 requirements for CSA/CSR and SDS under REACH in the same way as substances which are
41 dangerous because of their (eco-) toxicological properties.

42 Risk characterisation with regard to human health must be carried out as a minimum for explosivity,
43 flammability or oxidising potential. For those previously mentioned physicochemical properties, the
44 assessment shall entail an evaluation of the likelihood (risk) that an adverse effect will be caused
45 under the reasonably foreseeable conditions of use in the workplace or by consumers.

46 The assessment of the potential effects arising from the capacity of hazardous chemical agents to
47 cause accidents, in particular fires, explosions or other hazardous chemical reactions covers:

- 48 • hazards resulting from the physicochemical nature of the chemical agents,
- 49 • risk factors identified in their storage, transport and use, and
- 50 • the estimated severity in the event of occurrence.

51

52 E.2.2 Evaluation

53 The accident scenario's to be considered linked to REACH are minor accidents which might occur
54 in the workplace and those related to consumer use. As major accidents caused by chemicals and
55 the requirements to manage these risks are regulated under the Seveso II directive (Council
56 directive 98/82/EC¹) it can be assumed that major accident risks are adequately covered. It is
57 therefore unreasonable to expect catastrophic consequences to result from such accidents.
58 Simplified assessments, based on questionnaires and/or check lists, can be used to evaluate where
59 the risks are controlled. In general, the aim of these simplified assessments is not to calculate the
60 absolute value of the risk but to provide only an approximation of the magnitude of the risk. This
61 will often be sufficient to establish a risk hierarchy and thus determine the priorities in the
62 preventive action.

63 An example of such a simplified assessment including a questionnaire for the downstream user on
64 their use conditions has been developed by DG Employment in the context of Directive 98/24/E
65 (see explanation and questionnaire in Annex E-1). Based on the simplified assessment one can
66 either conclude that the use of the substance can be considered of no immediate concern or that
67 recommendations for risk reduction are necessary.

68 For more detail, see Section R.9.1.

69 E.2.3 Input

70 Substances having been classified based on their physicochemical properties are handled by many
71 M/I or DU industries since years and detailed methodologies to evaluate the risks associated with
72 handling of such substances under normal operational conditions or maintenance activities may
73 already be available and applicable to assess likelihood and potential severity of an accident (e.g.
74 HAZOP analysis used for Seveso II directive requirements). In case such methods are not known to
75 the registrant the simplified methodology explained in Annex E-1 can be applied.

76 Based on a set of standardized questions to be checked by the M/I an assessment of identified uses
77 based on a hazard rating scheme can be conducted. This assessment is, however, already based on
78 the identification and presetting of necessary risk management measures to control the risks and is
79 therefore a cross-check for the M/I whether the appropriate application of the recommended RMMs
80 at the DU level is suitable for eliminating / minimizing the likelihood of accidental events.

81 E.2.4 Output

82 Independently of the assessment method applied the M/I shall prepare an analysis of the processes
83 and procedures a hazardous substance is used in and describe the measures taken to prevent
84 accidental release or negative effects on human health in case of an event. This should include a
85 hazard ranking of the substance (e.g. using the R-phrases as criteria, see Table E.5-3 : Assessment
86 criteria) and a possible frequency and assumed severity of an accident. A rational judgement should
87 be provided which describes the underlying assumptions and the conclusions made.

¹ Further guidance see <http://mahbsrv.jrc.it/GuidanceDocs-SafetyManagementSystems.html#Section3-2>

88 **E.3 RISK CHARACTERISATION FOR HUMAN HEALTH**

89 **E.3.1 General aspects**

90 Having conducted the hazard assessment for all relevant human populations (Chapters R.1-R.8),
91 exposure assessment (Chapters R.13-R.18), either a quantitative or a qualitative risk
92 characterisation (see Chapter E.4.6 for details) is carried out. Endpoint specific issues, as for
93 example mutagenicity, carcinogenicity, sensitization, corrosivity, irritation, are described in Chapter
94 R.7.

95 Most risk characterisations for which a DNEL is not identified will be based on qualitative
96 considerations (see chapter E.4.6). However, it should be acknowledged that the whole risk
97 characterisation process, whether quantitative or qualitative, depends heavily upon expert
98 judgement. Therefore, the approach taken in reaching a conclusion needs to be as transparent as
99 possible and needs careful explanation/justification as to assumptions, decisions, uncertainties and
100 adequacy of the available data set.

101 **E.3.2 Step 1 and 2: collect hazard and exposure information**

102 Human risk characterisation is basically an integration of the findings from the exposure and effects
103 assessment in order to reach a characterisation of possible risks. A logical first step of a risk
104 characterisation is therefore to recap the main findings from the previous phases of the risk
105 assessment. Please note that the chapters on human health hazard assessment (R.1-R.8) contain
106 many risk characterisation considerations.

107 Subsequently, the derived DNEL or DMEL need to be matched with exposure estimates for
108 relevant exposure scenarios, ensuring that the parameters chosen from the effects and exposure
109 assessments lead to meaningful comparisons. This means that time scales, human populations,
110 endpoints of concern, and routes of exposure for the hazard and exposure information should match.

111 **E.3.3 Step 3: calculate the risk characterisation ratios**

112 The quantitative risk characterisation is carried out by comparing the estimated exposure with the
113 DNEL for threshold substances and the DMEL for non-threshold substances. This is done
114 separately for each of the following populations:

- 115 • Workers
- 116 • Consumers
- 117 • Humans exposed via the environment

118 and for all relevant exposure routes:

- 119 • inhalation
- 120 • dermal exposure
- 121 • oral intake

E.3.3.1 Workers

123 Various RCRs can be derived for workers. The following combinations of time scales and routes of
124 exposure can occur:

- 125 • Time scales: short-term (acute exposure) and long-term (chronic exposure).
- 126 • Routes of exposure: inhalation, dermal, inhalation and dermal combined.

127

128 Related to exposure pathways, the exposure is either expressed as external concentration C in air
129 (for inhalation) or as an uptake U , which is the amount of chemical taken up by the worker. In case
130 of combined exposure, a total uptake needs to be calculated. The uptake via inhalation is calculated
131 by multiplying the concentration in air with the worker inhalation rate ($I_{\text{inhalation,worker}}$).

132 RCR for workers = exposure/DNEL if a threshold effect is leading health effect (see section on
133 DNEL derivation, Chapter R.8).

134 RCR for workers = exposure/DMEL if a non-threshold effect is leading health effect (see section on
135 DMEL derivation, Chapter R.8).

136 Input

Parameter	Description	Source
$C_{x,y,z}$	Estimated concentration for workers x = route of exposure (inhalation) y = time scale (short-term, long-term) z = state of substance (vapour, fibre, dust)	Exposure, Chapter R.14
$U_{x,y}$	Potential dermal uptake for workers x = route of exposure (dermal) y = time scale (short-term, long-term)	
$U_{tot,y}$	Dermal + inhalation exposure (external) of workers y = time scale (short-term, long-term)	
$DNEL_{x,y}$	Derived No-Effect Level for workers x = route of exposure (inhalation, dermal) y = time scale (short-term, long-term)	DNEL/DMEL Chapter R.8
$DMEL_{x,y}$	Derived Minimal Effect Level for workers (if appropriate) x = route of exposure (inhalation, dermal) y = time scale (short-term, long-term)	

137

138 Output

Parameter	Description	Destination
$RCR_{x,y}$	Exposure /DNEL or Exposure /DMEL x = route of exposure (inhalation, dermal, total) y = time scale (short-term, long-term)	CSR

139 **E.3.3.2 Consumers**

140 The following combination of time scales and routes of exposure can occur:

- 141 • Time scales: short-term (acute exposure) and long-term (chronic exposure).
142 • Routes of exposure: inhalation, dermal and oral, all routes combined.

143

144 Related to exposure pathways, the exposure is either expressed as external concentration C (for
145 inhalation, dermal) or as an uptake, U (for oral uptake and dermal exposure), that is the external
146 amount potentially available for uptake. In case of combined exposure, a total uptake needs to be
147 calculated. The uptake via inhalation, $U_{inhalation}$, is calculated by multiplying the air concentration
148 with the consumer inhalation rate ($I_{inhalation,consumer}$).

149 RCR for consumers = exposure /DNEL if threshold effect is leading health effect150 RCR for consumers = exposure /DMEL if non-threshold effect is leading health effect

151 Input

Parameter	Description	Source	
$C_{x,y}$	Estimated concentration for consumers x = route of exposure (inhalation, dermal, oral) y = exposure duration (short-term, long-term)	Exposure Chapter R.15	
$U_{x,y}$	Potential dermal uptake for consumers x = route of exposure (dermal) y = exposure duration (short-term, long-term)		
$I_{x,y}$	Ingestion rate for consumers x = route of exposure (oral) y = exposure duration (short-term, long-term)		
$U_{tot,y}$	Total potential uptake via all routes of exposure for consumers y = exposure duration (short-term, long-term)		
$DNEL_{x,y}$	Derived No-Effect Level for consumers x = route of exposure (inhalation, dermal, oral, total) y = exposure duration (short-term, long-term)		DNEL/DMEL Chapter R.8
$DMEL_{x,y}$	Derived Minimal Effect Level for consumers (if appropriate) x = route of exposure (inhalation, dermal, oral, total) y = exposure duration (short-term, long-term)		

152

153 Output

Parameter	Description	Destination
$RCR_{x,y}$	Exposure /DNEL or Exposure /DMEL x = route of exposure (inhalation, dermal, oral, total) y = time scale (short-term, long-term)	

154 **E.3.3.3 Humans exposed via the environment**

155 Only inhalation and oral intake is considered relevant for this population. Chapter R.16 gives a
 156 description of the derivation of the human exposure via oral intake. The uptake (U) is calculated by
 157 multiplying the intake rate of the media with concentration in the media. The concentration in the
 158 intake medium (air) can be calculated with environmental distribution models of Chapter R.16. The
 159 uptake via inhalation can be derived by multiplying the inhalation rate for humans, $I_{Inhalation, HEvE}$,
 160 with the air concentration.

161 The following combination of time scales and routes of exposure can occur for Human Exposure
 162 via the environment (HEvE):

- 163 • Time scales: long-term (chronic exposure).
- 164 • Routes of exposure: inhalation, oral, inhalation and oral combined.

165 Relevant endpoints HEvE are only chronic endpoints, i.e. repeated dose toxicity,
 166 mutagenicity/carcinogenicity (unless via a non-threshold mode of action) and reproductive toxicity.

167 RCR for humans exposed via the environment for threshold substances = $U/DNEL$ or
 168 $PEC_{air}/DNEL$.

169 RCR for humans exposed via the environment for non-threshold substances with a DMEL (if
 170 appropriate) is exposure/DMEL or $PEC_{air}/DMEL$. Time scales and routes are similar to those for
 171 substances with a threshold mode of action.

172 Input

Parameter	Description	Source
$C_{x,y}$	Estimated concentration for HEvE x = route of exposure (inhalation, oral) y = exposure duration (long-term) z = media: air, crop, milk, meat, fish, drinking water	Environmental Exposure, Chapter R.16
$I_{x,y}$	Ingestion rate for HEvE x = route of exposure (oral) y = exposure duration (long-term)	DNEL/DMEL Chapter R.8
$DNEL_{x,y}$	Derived No-Effect Level for HEvE x = route of exposure (inhalation, oral) y = exposure duration (long-term)	
$DMEL_{x,y}$	Derived Minimal Effect Level for HEvE x = route of exposure (inhalation, oral) y = exposure duration (long-term)	

173

174 Output

Parameter	Description	Destination
$RCR_{x,y}$	Exposure /DNEL or Exposure /DMEL x = route of exposure (inhalation, oral) y = time scale (long-term)	pm

175 **E.4 RISK CHARACTERISATION FOR THE ENVIRONMENT**176 **E.4.1 General aspects**

177 Having conducted the hazard assessment for all environmental compartments (Part B, Chapter
178 R.10) and the exposure assessment (Chapter R.16) either a quantitative or a qualitative risk
179 characterisation (see chapter E.4.6 for details on this) is carried out.

180 The quantitative risk characterisation is carried out by comparing the PEC with the PNEC. This is
181 done separately for each of the following environmental protection targets:

182 Inland environmental protection targets:

- 183 • aquatic ecosystem;
- 184 • terrestrial ecosystem;
- 185 • atmosphere;
- 186 • predators (fish- and worm-eating);
- 187 • micro-organisms in sewage treatment plants

188

189 Marine environmental protection targets:

- 190 • aquatic ecosystem;
- 191 • predators and top predators.

192 **E.4.2 Step 1 and 2: collect hazard and exposure information**

193 The effect values are expressed as the Predicted No effect concentrations, the PNECs, which are
 194 derived for all relevant environmental compartments. The derivation of the PNECs is described in
 195 part B and Chapter R.10. Please note that the chapters on environmental hazard assessment (R.7 and
 196 R.10) contain many risk characterisation considerations. The environmental exposure is expressed
 197 as environmental concentrations, i.e. the PECs. The derivation of the PECs for the relevant
 198 environmental compartments is described in Chapter R.16.

199 **E.4.3 Step 3: Calculate the risk characterisation ratios**

200 A list of the different PEC/PNEC ratios that should be considered for the inland and marine
 201 environments is given in Table E.4-1 and Table E.4-2, respectively.

202 **Table E.4-1 Overview of PEC/PNEC ratios considered for inland risk assessment ***

Local	Regional
$PEC_{local,water}/PNEC_{water}$	$PEC_{regional,water}/PNEC_{water}$
$PEC_{local,sediment}/PNEC_{sediment}$	$PEC_{regional,sediment}/PNEC_{sediment}$
$PEC_{local,soil}/PNEC_{soil}$	$PEC_{regional,agr.soil}/PNEC_{soil}$
$PEC_{stp}/PNEC_{microorganisms}$	
$(0.5 \cdot PEC_{local,oral_{fish}} + 0.5 \cdot PEC_{regional,oral_{fish}})/PNEC_{Coral}$	
$(0.5 \cdot PEC_{local,oral_{worm}} + 0.5 \cdot PEC_{regional,oral_{worm}})/PNEC_{Coral}$	

203 * It must be noted that these ratios are to be derived for all stages of the life-cycle of a compound.

204 **Table E.4-2 Overview of PEC/PNEC ratios considered for marine risk assessment ***

Local	Regional
$PEC_{local,seawater}/PNEC_{saltwater}$	$PEC_{regional,seawater}/PNEC_{saltwater}$
$PEC_{local,sediment}/PNEC_{marine\ sediment}$	$PEC_{regional,sediment}/PNEC_{marine\ sediment}$
$[(PEC_{local,seawater,ann} + PEC_{regional,seawater}) \cdot 0.5 \cdot BCF_{fish} \cdot BMF_1]/PNEC_{Coral_{predator}}$	
$[(0.1 \cdot PEC_{local,seawater,ann} + 0.9 \cdot PEC_{regional,seawater}) \cdot BCF_{fish} \cdot BMF_1 \cdot BMF_2]/PNEC_{Coral_{top\ predator}}$	

205 * It must be noted that these ratios are to be derived for all stages of the life-cycle of a compound.
 206

207 For the air compartment usually only a qualitative assessment of abiotic effects is carried out. If
 208 there are indications that one or more of these abiotic effects occur for a given substance, expert
 209 knowledge should be consulted or the substance be handed over to the relevant international group,
 210 e.g. to the responsible body in the United Nations Environment Programme (UNEP) for ozone
 211 depleting substances. In some cases also an assessment of the biotic effects to plants can be carried
 212 out.

213 If a refinement of the risk characterisation is possible but the necessary data are not available,
 214 further information and/or testing may be required. A decision must be taken as to whether both the
 215 PEC and PNEC will be iterated or only one of them. If additional information needs to be
 216 generated, it should be based on the principles of lowest cost and effort, highest gain of information
 217 and the avoidance of unnecessary testing on animals.

218 E.4.3.1 Aquatic environment

219 The concentration of the chemical in surface water is compared to the no-effect concentration for
 220 aquatic organisms. This is done for the local as well as the regional freshwater and marine
 221 environment. On the local scale, the concentration during an emission episode is taken. It should be
 222 noted that the local ratios have to be defined for all relevant stages of the life cycle and for each
 223 application of the substance.

$$RCR_{local,water} = \frac{PEC_{local,water}}{PNEC_{water}} \quad \text{Equation E-2}$$

$$RCR_{local,water,marine} = \frac{PEC_{local,water,marine}}{PNEC_{water,marine}} \quad \text{Equation E-3}$$

$$RCR_{reg,water} = \frac{PEC_{reg,water}}{PNEC_{water}} \quad \text{Equation E-4}$$

$$RCR_{reg,water,marine} = \frac{PEC_{reg,water,marine}}{PNEC_{water,marine}} \quad \text{Equation E-5}$$

224	Input		
225	PEC _{local,water}	local PEC in surface water during emission episode	[kg _c .m ⁻³]
226	PEC _{reg,water}	regional steady-state PEC in surface water	[kg _c .m ⁻³]
227	PEC _{local,water,marine}	local PEC in marine water during emission episode	[kg _c .m ⁻³]
228	PEC _{reg,water,marine}	regional steady-state PEC in marine surface water	[kg _c .m ⁻³]
229	PNEC _{water}	PNEC for aquatic compartment	[kg _c .m ⁻³]
230	PNEC _{water,marine}	PNEC for marine aquatic compartment	[kg _c .m ⁻³]
231	Output		
232	RCR _{local,water}	RCR for local water compartment	[-]
233	RCR _{reg,water}	RCR for regional water compartment	[-]
234	RCR _{local,water,marine}	RCR for local marine water compartment	[-]
235	RCR _{reg,water,marine}	RCR for regional marine water compartment	[-]

236 E.4.3.2 Terrestrial compartment

237 The concentration of the chemical in agricultural soil is compared to the no-effect concentration for
 238 terrestrial organisms. This is done for the local as well as the regional environment. On the local
 239 scale, the concentration averaged over 30 days is used. It should be noted that the local ratios have
 240 to be defined for all relevant stages of the life cycle and for each application of the substance. For
 241 substances with a log *K_{ow}* greater than 5, the equilibrium-partitioning method is used in a modified
 242 way. For these substances, the PEC/PNEC in soil is increased by a factor of 10 to account for
 243 uptake via ingestion of soil.

$$RCR_{local\ soil} = \frac{PEC_{local\ soil}}{PNEC_{soil}} \quad \text{Equation E-6}$$

244

$$RCR_{reg\ soil} = \frac{PEC_{reg\ agric}}{PNEC_{soil}} \quad \text{Equation E-7}$$

245

246 If $EP_{terr} = \text{yes}$ and $\log Kow > 5$ then

$$RCR_{local\ soil} = \frac{PEC_{local\ soil}}{PNEC_{soil}} \cdot 10 \quad \text{Equation E-8}$$

247

248 If $EP_{terr} = \text{yes}$ and $\log Kow > 5$ then

$$RCR_{reg\ soil} = \frac{PEC_{reg\ agric}}{PNEC_{soil}} \cdot 10 \quad \text{Equation E-9}$$

249

250 **Input**251 $PEC_{local\ soil}$

local PEC in agricultural soil, averaged over 30 days

[kg_c·kg_{wwt}⁻¹]252 $PEC_{reg\ agric}$

regional steady-state PEC in agricultural soil

[kg_c·kg_{wwt}⁻¹]253 $PNEC_{soil}$

PNEC for soil compartment

[kg_c·kg_{wwt}⁻¹]254 EP_{terr}

equilibrium partitioning used for PNEC?

[yes/no]

255 **Output**256 $RCR_{local\ soil}$

RCR for local soil compartment

[-]

257 $RCR_{reg\ soil}$

RCR for regional soil compartment

[-]

258 **E.4.3.3 Sediment compartment**

259 The concentration of the chemical in sediment is compared to the no-effect concentration for
 260 sediment-dwelling organisms. This is done for the local as well as the regional freshwater and
 261 marine environment. It should be noted that the local ratios have to be defined for all relevant stages
 262 of the life cycle and for each application of the substance. For substances with a $\log Kow$ greater
 263 than 5, the equilibrium-partitioning method is used in a modified way. For these substances, the
 264 PEC/PNEC in sediment is increased by a factor of 10 to account for uptake via ingestion of
 265 sediment. It should be noted that a risk characterisation for sediment is only feasible if measured
 266 data are used to overwrite the estimates for PEC and/or PNEC in sediment (otherwise, equilibrium
 267 partitioning is applied to derive both PEC and PNEC).

$$RCR_{local\ sed} = \frac{PEC_{local\ sed}}{PNEC_{sed}} \quad \text{Equation E-10}$$

268

$$RCR_{local\ sed, marine} = \frac{PEC_{local\ sed, marine}}{PNEC_{sed, marine}} \quad \text{Equation E-11}$$

269

$$RCRreg_{sed} = \frac{PECreg_{sed}}{PNEC_{sed}} \quad \text{Equation E-12}$$

270

$$RCRreg_{sed,marine} = \frac{PECreg_{sed,marine}}{PNEC_{sed,marine}} \quad \text{Equation E-13}$$

271

272 If $EP_{sed} = \text{yes}$ and $\log Kow > 5$ then:

$$RCRlocal_{sed} = \frac{PEClocal_{sed}}{PNEC_{sed}} \cdot 10 \quad \text{Equation E-14}$$

273

$$RCRreg_{sed} = \frac{PECreg_{sed}}{PNEC_{sed}} \cdot 10 \quad \text{Equation E-15}$$

274

275 If $EP_{sed,marine} = \text{yes}$ and $\log Kow > 5$ then:

$$RCRlocal_{sed,marine} = \frac{PEClocal_{sed,marine}}{PNEC_{sed,marine}} \cdot 10 \quad \text{Equation E-16}$$

276

$$RCRreg_{sed,marine} = \frac{PECreg_{sed,marine}}{PNEC_{sed,marine}} \cdot 10 \quad \text{Equation E-17}$$

277

Input		
278	$PEC_{local, sed}$	local PEC in sediment [kg _c ·kg _{wwt} ⁻¹]
279	$PEC_{local, sed, marine}$	local PEC in marine sediment [kg _c ·kg _{wwt} ⁻¹]
280	$PEC_{reg, sed}$	regional steady-state PEC in sediment [kg _c ·kg _{wwt} ⁻¹]
281	$PEC_{reg, sed, marine}$	regional steady-state PEC in marine sediment [kg _c ·kg _{wwt} ⁻¹]
282	$PNEC_{sed}$	PNEC for the sediment compartment [kg _c ·kg _{wwt} ⁻¹]
283	$PNEC_{sed, marine}$	PNEC for the marine sediment compartment [kg _c ·kg _{wwt} ⁻¹]
284	EP_{sed}	equilibrium partitioning used for PNEC for sediment? [yes/no]
285	$EP_{sed, marine}$	equilibrium partitioning used for PNEC for marine sediment? [yes/no]
286	Kow	octanol-water partition coefficient [m ³ ·m ⁻³]
287	Output	
288	$RCR_{local, sed}$	RCR for local sediment compartment [-]
289	$RCR_{local, sed, marine}$	RCR for local marine sediment compartment [-]
290	$RCR_{reg, sed}$	RCR for regional sediment compartment [-]
291	$RCR_{reg, sed, marine}$	RCR for regional marine sediment compartment [-]

292 E.4.3.4 Micro-organisms in STP

293 The concentration of the chemical in the sewage treatment plant is compared to the no-effect
 294 concentration for micro-organisms. This is done for the local environment only. The concentration
 295 during an emission episode is used. It should be noted that the ratios have to be defined for all
 296 relevant stages of the life cycle and for each application of the substance.

$$RCR_{stp} = \frac{PEC_{stp}}{PNEC_{micro-organisms}} \quad \text{Equation E-18}$$

297			
298	Input		
299	PEC _{stp}	local PEC in STP during emission episode	[kg.c.m ⁻³]
300	PNEC _{micro-organisms}	PNEC for STP micro-organisms	[kg.c.m ⁻³]
301	Output		
302	RCR _{stp}	RCR for sewage treatment plant	[-]
303			

304 E.4.3.5 Predators in freshwater and marine environment

305 The concentration of the chemical in fish and in fish-eating predators is compared to the no-effect
 306 concentration for birds and mammals. Local and regional concentrations are combined for
 307 calculating the concentration in fish and fish-eating predators. It should be noted that the ratios have
 308 to be defined for all relevant stages of the life cycle and for each application of the substance.

$$RCR_{oral, fish} = \frac{PEC_{oral, fish}}{PNEC_{oral}} \quad \text{Equation E-19}$$

309

$$RCR_{oral, fish, marine} = \frac{PEC_{oral, fish, marine}}{PNEC_{oral}} \quad \text{Equation E-20}$$

310

$$RCR_{oral, fish predator, marine} = \frac{PEC_{oral, fish predator, marine}}{PNEC_{oral}} \quad \text{Equation E-21}$$

311			
312	Input		
313	PEC _{oral, fish}	PEC in fish (local and regional combined)	[kg.c.kg _{wwt} ⁻¹]
314	PEC _{oral, fish, marine}	PEC in marine fish (local and regional combined)	[kg.c.kg _{wwt} ⁻¹]
315	PEC _{oral, fish predator, marine}	PEC in marine fish-eating predator (local and regional combined)	[kg.c.kg _{wwt} ⁻¹]
316	PNEC _{oral}	PNEC for birds and mammals	[kg.c.kg _{wwt} ⁻¹]
317	Output		
318	RCR _{oral, fish}	RCR for fish-eating birds/mammals (freshwater environment)	[-]
319	RCR _{oral, fish, marine}	RCR for fish-eating birds/mammals (marine environment)	[-]
320	RCR _{oral, fish predator, marine}	RCR for top-predators (marine environment)	[-]

321 E.4.3.6 Worm-eating predators

322 The concentration of the chemical in earthworms is compared to the no-effect concentration for
 323 birds and mammals. There is only one concentration in earthworms as local and regional are
 324 combined in this concentration. It should be noted that the ratios have to be defined for all relevant
 325 stages of the life cycle and for each application of the substance.

$$RCR_{oral, worm} = \frac{PEC_{oral, worm}}{PNEC_{oral}} \quad \text{Equation E-22}$$

326	Input		
327	PEC _{oral,worm}	PEC in worm (local and regional combined)	[kg _c .kg _{wwt} ⁻¹]
328	PNEC _{oral}	PNEC for birds and mammals	[kg _c .kg _{wwt} ⁻¹]
329	Output		
330	RCR _{oral,worm}	RCR for worm-eating birds and mammals	[-]

331 E.4.4 Step 4: combined exposures

332 In situations where the same person is potentially exposed to the same substance in the same setting
 333 via different routes of entry into the body or from different products containing the same substance,
 334 exposure scenarios reflecting these concomitant exposures should be assessed in the exposure
 335 estimation. These scenarios – typically related to workplaces and aggregated exposure for
 336 consumers – need specific attention in the risk characterisation step.

337 In addition, humans are exposed at work, from consumer products and via environmental
 338 exposures. It should be considered in which cases it is relevant to make risk characterisation for
 339 such scenarios, representing exposure from all sources. Typically it is most relevant to combine
 340 consumer exposures with indirect exposure of humans via the environment.

341 In special cases, where exposure occurs to a substance as well as to several very closely related and
 342 similar acting chemical substances (e.g. different salts of a metal or closely related derivatives of
 343 organic substances), the exposure evaluation and risk characterisation should reflect this aspect. If
 344 data are available the exposure assessment should also include a scenario concerning this combined
 345 exposure. One way to conduct risk characterisation for combined exposure to closely related
 346 analogues could be to add exposures and to use a toxicological descriptor from a representative
 347 substance among the analogues. If data do not allow for a quantitative assessment, an attempt
 348 should be made to address the issue in a qualitative way.

349 A list of the different exposure/DNEL or exposure/DMEL ratios that should be considered for the
 350 human populations is given in Chapter R.8.

351 E.4.5 Step 5: Decide on possible iterations of the CSA

352 In this step, a decision should be made on possible iterations of the CSA (see Section A.2.6 and
 353 D.7), taking uncertainties in the assessment into account (see Chapter R.19). For populations and
 354 environmental spheres where control of risk cannot be demonstrated, iterations of the CSA for these
 355 parts may be needed. One or more of the following options are available:

- 356 • Improve exposure information and/or consider to introduce sufficient RMMs
- 357 • Improve hazard information
- 358 • Conclude that it is not possible to demonstrate control of risk, and make the necessary
 359 documentation that uses are advised against

360 E.4.5.1 Uncertainty analysis

361 This phase of the CSA is the most logical place to consider the overall uncertainties that are noticed
 362 and recorded in the preceding phases of the CSA:

- 363 - Both hazard and exposure assessment carry a degree of uncertainty that is integrated in the RCR

- 364 - The uncertainty in the outcome of a CSA iteration is relevant information that can be used to
365 decide if risks are controlled or that too much uncertainty is still associated with it which needs
366 to be addressed in further iterations of the CSA
367

368 Quantifying uncertainty in the RCR may help in making more rational decisions on control of risks.
369 It is therefore proposed to use uncertainty analysis (see Chapter R.19) to determine if the RCR is a
370 robust estimate of (relative) risk. The advantage of an uncertainty analysis is that in principle, all
371 available data contribute to the analysis and transparency and credibility are improved. Chapter
372 R.19 provides a tiered assessment, including relatively simple assessments to focus the assessment
373 on the main uncertainties.

374 **E.4.6 Step 6: Finalize CSA**

375 The CSA can be finalised if the risk characterisation demonstrates control of risks for all
376 populations and end-points or if it is concluded that it is not possible to demonstrate control of risk.

377 **E.5 QUALITATIVE RISK CHARACTERISATION**

378 **E.5.1 Human exposure²**

379 A qualitative risk characterisation has to be completed when there is no basis for setting a DNEL or
380 DMEL, i.e. when the available data does not provide quantitative dose-response data, but toxicity
381 information is of a qualitative nature. The types of qualitative data that may be available for
382 different endpoints are indicated below. The purpose of the qualitative risk characterisation is to
383 assess '*the likelihood that effects are avoided when implementing the exposure scenario*' (REACH
384 Annex 1, section 6.5). The endpoints for which the available data may often trigger a qualitative
385 risk characterisation are: Irritation/corrosion, sensitisation, acute toxicity and
386 carcinogenicity/mutagenicity.

387 **E.5.2 Environment**

388 When no quantitative risk characterisation can be carried out, for example for remote marine areas
389 or when either PEC or PNEC cannot be properly derived, a qualitative risk characterisation should
390 be conducted.

391 For a qualitative assessment of risks for PBT and vPvB substances, the approach should be used as
392 described in Chapter R.11.2.2. A human health hazard assessment or environmental hazard
393 assessment in accordance with REACH, Annex I, and the estimation of the long-term exposure of
394 humans and the environment (Annex I, Section 5) cannot be carried out with sufficient reliability
395 for substances satisfying the PBT and vPvB criteria. This necessitates a separate PBT and vPvB
396 assessment. Substances fulfilling the PBT criteria regarding Persistence, Bioaccumulation and
397 Toxicity are of priority for further risk management consideration. For such substances, an
398 evaluation of the sources, major emissions and pathways to the marine environment should take
399 place in order to sufficiently establish the most appropriate and effective measures to reduce the
400 releases to the marine environment. The CSA will always include the PBT and vPvB assessment to
401 determine if the substance fulfils the criteria given in REACH, Annex XII and if so, to characterise
402 the potential emissions of the substance (see Part C and Chapter R.11).

² This section is incomplete and will be based on Appendix 13 of chapter R.8.

403 For some substances it may not be possible to undertake a full quantitative risk assessment, using a
404 $PEC_{\text{water}}/PNEC_{\text{water}}$ ratio because of the inability to calculate a $PNEC_{\text{water}}$. This can occur when no
405 effects are observed in short-term tests. However, an absence of short-term toxicity does not
406 necessarily mean that a substance has no long-term toxicity, particularly when it has low water
407 solubility and/or high hydrophobicity. For such substances, the concentration in water (at the
408 solubility limit) may not be sufficient to cause short-term effects because the time to reach a steady-
409 state between the organism and the water is longer than the test duration.

410 For these substances, therefore, it is recommended to conduct a qualitative risk assessment in order
411 to decide if further long-term testing is required. Such an assessment should take full account of the
412 level of exposure (PEC_{local} or PEC_{regional} , as appropriate) as well as of the probability that long-
413 term effects may occur despite the absence of short-term effects. Thus, especially for non-polar
414 organic substances with a potential to bioaccumulate ($\log K_{ow} > 3$), the need for long-term testing
415 is more compelling. For ionised substances or surfactants the determination of a trigger value on the
416 basis of other physicochemical properties, e.g. K_d should be sufficient to ask for long-term tests.
417 Taking all this into account, long-term toxicity tests should be asked for immediately for substances
418 with $\log K_{ow} > 3$ (or $BCF > 100$) and a PEC_{local} or $PEC_{\text{regional}} > 1/100^{\text{th}}$ of the water solubility.

419 The water solubility should, where possible, be based on the solubility in the aquatic toxicity test
420 water rather than distilled water (presuming that this solubility is measured after filtration ($0.45 \mu\text{m}$)
421 of the test solution or after centrifugation). When the $\log K_{ow}$ is not a good indicator of
422 bioconcentration, or where there are other indications of a potential to bioconcentrate (see Section
423 R.7.10), a case-by-case assessment of the presumable long-term effects will be necessary.

424 **APPENDIX E-1. QUESTIONNAIRES FOR ASSESSING THE RISK OF ACCIDENT, FIRE**
 425 **AND EXPLOSION**

426 A questionnaire for assessing the risk of accident, fire and explosion due to the presence of
 427 hazardous substances (DG EMPL) is included below:

428 **SIMPLIFIED METHODOLOGY FOR ASSESSING THE RISK OF ACCIDENT, FIRE**
 429 **AND EXPLOSION DUE TO THE PRESENCE OF HAZARDOUS SUBSTANCES (DG**
 430 **EMPL)**

431 General introduction

432 The methodology explained below may help M/I for identifying the hazards and assessing the risks
 433 associated with using hazardous substances so that an evaluation of likelihood and possible
 434 consequences of an accident can be done objectively.

435 This methodology, applied specifically to the risk associated with storing and using hazardous
 436 chemical agents, focuses on the predicted damage and not on the maximum damage. It incorporates
 437 and develops the experience in applying simplified methodologies based on estimating the
 438 probability of occurrence of the hazardous situation analysed, the frequency of exposure to this and
 439 the consequences normally expected if this situation does occur. These parameters are used by the
 440 W.T. Fine method and by various methods developed by the INSHT (Instituto Nacional de
 441 Seguridad e Higiene en el Trabajo – Spanish National Institute for Health and Safety at Work).
 442 They are also the criteria used by some harmonised standards produced by the CEN, including EN
 443 1050 and EN 1127-1.

444 The proposed methodology will allow the magnitude of the existing risks to be quantified and
 445 consequently will allow their priority for correction to be rationally determined. It therefore starts
 446 with the identification of existing deficiencies in the installations, equipment, processes, tasks, etc.
 447 involving hazardous substances. These deficiencies or non-compliances are related to the R phrases
 448 assigned to the various substances involved, thus obtaining the objective hazard rating (OHR) for
 449 the situation. The level of exposure to the identified hazard rating is then established and, taking
 450 into account the predicted magnitude of the consequences (the consequences normally expected
 451 must be pre-established by the person applying the methodology), the risk is assessed and the
 452 estimated level of risk for the situation assessed is obtained.

453 This method therefore determines the level of risk as the product of three variables:

$$454 \quad \quad \quad LR = OHR \times LE \times LC$$

455 Where LR: level of risk
 456 OHR: objective hazard rating
 457 LE: level of exposure
 458 LC: level of consequences

459
 460 The information provided by this method is intended for guidance only, its aim being to help
 461 employers to prioritise their prevention actions based on objective criteria and consequently to help
 462 them in the planning of prevention. The process for estimating the variables mentioned is described
 463 below.

464 Objective hazard rating

465 The extent of the link predicted between the set of risk factors taken into account and their direct
 466 causal relationship with a possible accident is referred to as the objective hazard rating (OHR). The
 467 numerical values used in this methodology and their meanings are shown in Table 1.

468 **Table E.5-1 : Determination of the objective hazard rating (OHR)**

OBJECTIVE HAZARD	OHR	MEANING
Acceptable	-	No significant anomalies have been detected. The risk is controlled if measures are implemented accordingly.
Improvable	2	Risk factors of minor importance have been detected. The set of existing prevention measures in relation to the risk could be improved.
Deficient	6	Risk factors which need to be corrected have been detected. The set of existing prevention measures in relation to the risk does not guarantee sufficient control of the risk.
Very Deficient	10	Significant risk factors have been detected. The set of existing prevention measures in relation to the risk is ineffective.

469
 470 It is proposed that a questionnaire (Table E.9-2), supplemented by Table E.9-3, is used to assess the
 471 OHR. Each question in the questionnaire is assigned, depending on the response, to a rating which
 472 in some cases is independent of the substance involved (and is indicated in the questionnaire itself)
 473 but which generally depends on the R phrases assigned to the substance.

474 Therefore, for example, a negative response to Question 5 will lead to a rating of improvable if the
 475 substance is assigned phrase R21 or to a rating of very deficient if it is assigned any of phrases R1
 476 to R6.

477 The questionnaire is intended to check the degree of compliance through a number of questions
 478 which are presumed to be fundamental when establishing the level of deficiency in installations,
 479 equipment, processes, tasks, etc., involving hazardous substances. It will obviously be necessary to
 480 refine its content by replacing or supplementing the questions asked with others meeting the legal or
 481 regulatory requirements in individual countries or the situation or needs of the undertaking applying
 482 this.

483 In addition, those questions intended to identify deficiencies where non-compliance may give rise to
 484 a fire or explosion (deficient or insufficient control of fuel and sources of ignition) may be separated
 485 from the questionnaire. The data obtained from these questions will determine the probability of
 486 occurrence which, when assessed together with the degree of compliance with the fire protection
 487 measures required by regulation, will provide information on the level of the fire risk. In this way,
 488 the assessment of the fire or explosion risk will be clarified and extended.

489 Therefore, each question results in a rating which may be “very deficient”, “deficient” or
 490 “improvable” (if the question is applicable) in line with the risk factors present and the intrinsic
 491 hazard of the substance which is known from its R risk phrases. No rating is given for Question 1

492 which is asked as a “key” question, since a negative response would mean that there were no
 493 hazardous substances in use and it would therefore not be necessary to continue with the
 494 questionnaire.

495 Depending on all the responses, an overall rating of the deficiency level is obtained which may be
496 “very deficient”, “deficient”, “improvable” or “acceptable” according to the following criteria:

- 497 a. The overall rating will be “very deficient” if any of the questions are rated as “very deficient”
498 or if more than 50% of the applicable questions receive the rating of “deficient”.
- 499 b. The overall rating will be “deficient” if, while not being “very deficient”, any of the questions
500 are rated as “deficient” or if more than 50% of the applicable questions receive the rating of
501 “improvable”.
- 502 c. The overall rating will be “improvable” if, while not being “very deficient” or “deficient”, any
503 of the questions are rated as “improvable”.
- 504 d. The overall rating will be acceptable in other cases.

505

506

Table E.5-2 : Check questionnaire for identifying accident risk factors due to physicochemical properties

	YES	NO	Proc No	Negative response implies	Rating
1. Do you store, use, produce, etc. substances in the form of raw materials, intermediate products, by-products, finished products, waste, cleaning products, etc.				The questionnaire must not be completed	
Identification of classified substances					
2. Are substances present during work, either on a regular basis or occasionally, identified and inventoried?					VERY DEFICIENT
3. Is the original packaging of classified substances correctly labelled?					VERY DEFICIENT
4. Is the above labelling kept when the substance is transferred to other packaging or containers?					VERY DEFICIENT
5. Have labels identifying the substance and direction of flow of liquids been stuck, attached or painted on pipes carrying classified substances.				Go to Table 3	
6. Have labels been placed along the pipe in sufficient numbers and in areas of special risk (valves, connections, etc.)					IMPROVABLE
7. Is a safety data sheet (SDS) available for all hazardous substances which are or may be present during work and, if necessary, is there sufficient and appropriate information on those substances without SDSs (waste, intermediate products, etc.)				Go to Table 3	
Storage/packaging of chemical agents					
8. Are substances stored in special enclosures grouped by risk category and adequately isolated (by distance or by partition) from incompatible substances or substances that may give rise to hazardous reactions?				Go to Table 3	
9. Is the storage area properly ventilated by either natural or forced draught?					DEFICIENT
10. When required due to the product quantity and/or hazard, is the collection and removal of liquid substance leaks or spillages to a safe container or area ensured in storage, use and/or production areas.					DEFICIENT
11. Is the presence or use of "uncontrolled" ignition sources in flammable substances stores banned and is compliance with this ban exhaustively monitored and assured?				Go to Table 3	
12. Does packaging containing such substances offer sufficient physical or chemical resistance and is it free of any signs of impacts, cuts or deformations.				Go to Table 3	

	YES	NO	Proc No	Negative response implies	Rating
13. Is packaging containing such substances totally secure (automatic closure, safety closure with interlock, double wrapping, shock absorbent coating, etc.)				Go to Table 3	
14. Is packaging transported, whether by manual or mechanical means, using equipment and/or implements that ensure that this is stable and properly secured?				Go to Table 3	
Substance use/process					
15. Is only the quantity such substances strictly necessary for the immediate work kept in the workplace (never quantities greater than those needed for the shift or working day).					IMPROVABLE
16. Are substances present in the workplace for use during the shift or working day and those not currently in use stored in appropriate containers, protected cabinets or special enclosures.					IMPROVABLE
17. Is the transfer of such substances by open pouring avoided?				Go to Table 3	
18. Is the creation and/or accumulation of static discharges during the transfer of flammable liquids rigorously monitored?				Go to Table 3	
19. Is the electrical installation in areas with a risk of flammable atmospheres explosion-proof and are ignition sources of any kind also monitored ⁺ .				Go to Table 3	
20. Is the electrical installation of corrosive product equipment, instruments, rooms and stores adequate?				Go to Table 3	
21. Are the characteristics of materials, equipment and tools appropriate for the nature of the substances used.				Go to Table 3	
22. Is the absence of leaks and, in general, the correct state of installations and/or equipment checked before use.				Go to Table 3	
23. Do equipment or processes requiring this have systems to detect unsafe conditions (LIL level in drying tunnel, reactor temperature/pressure, fill level of a tank, etc.) associated with an alarm system.				Go to Table 3	
24. Do existing detection systems act to shut down the process when required by critical situations?					DEFICIENT
25. Are vents and outlets of safety devices for flammable/explosive products channelled to a safe place and equipped with flares where required.				Go to Table 3	
26. Are devices available for the safe treatment, absorption, destruction and/or containment of effluent from safety devices and vents?				Go to Table 3	
27. Are operations that involve the possible release of gas, vapour, dust, etc. carried out using closed processes or, failing this, in well-ventilated areas or in installations with local extraction systems.				Go to Table 3	
28. In general, have the collective protection measures needed to isolate such substances and/or limit				Go to Table 3	

	YES	NO	Proc No	Negative response implies	Rating
exposure and/or contact by workers been implemented.					
Organisation of prevention in the use of hazardous substances					
29. Is work authorisation required when carrying out operations involving a risk on containers, equipment or installations containing or which have contained substances?				Go to Table 3	
30. Is the control of access by external or unauthorised personnel to areas where substances are stored, loaded/unloaded or processed guaranteed?				Go to Table 3	
31. Have workers been properly informed about the risks associated with substances and correctly trained in the prevention and protection measures to be adopted.				Go to Table 3	
32. Do workers have access to the SDS provided by the supplier?					IMPROVABLE
33. Are written work procedures available for the performance of tasks involving hazardous substances?				Go to Table 3	
34. Is there a preventive maintenance programme and also a predictive maintenance programme for equipment or installations whose correct operation is crucial to process safety?					DEFICIENT
35. Is the cleanliness of workplaces and work posts ensured? (Has a programme been set up and is its application monitored).					IMPROVABLE
36. Are specific means available for neutralising and cleaning up spillages and/or for controlling leaks and do action instructions exist?					DEFICIENT
37. Is there a waste management plan and is its application monitored?					DEFICIENT
38. Have correct personal hygiene rules been implemented (hand washing, changing of clothes, ban on eating, drinking or smoking at work posts, etc) and is their application monitored?					IMPROVABLE
39. Is an Emergency Plan available for critical situations in which substances are involved (leaks, spillages, fire, explosion, etc.)					VERY DEFICIENT
40. In general, have the organisational measures required in order to isolate hazardous substances and/or limit exposure and/or contact by workers with these been implemented.				Go to Table 3	
Use of PPE and emergency installations					
41. Is the necessary personal protective equipment (PPE) available and is its effective use monitored in the various tasks at risk of exposure to, or contact with, substances.				Go to Table 3	

	YES	NO	Proc No	Negative response implies	Rating
42. Are decontaminating showers and eyebath fountains available close to places where substance splashes are possible.				Go to Table 3	
43. In general, is PPE and work clothing correctly managed?					DEFICIENT
44. Have any other deficiencies or shortcomings been detected with regard to collective protection, organisational measures and use of PPE: Describe and assess.					

507 * Open questionnaire proposed as a guide; under no circumstances should this be regarded as exhaustive and closed.

508 †To determine whether there is a risk of an explosive atmosphere, the work area should firstly be classified according to the presence of flammable substances and, where
 509 applicable, this should be checked using an explosion meter.

510

Table E.5-3 : Assessment criteria

Question n°	VERY DEFICIENT	DEFICIENT	IMPROVABLE
5,7 8	R1 to R6, R7, R12, R14, R15, R16, R17, R19, R27, R28, R35, R39	R8, R9, R11, R18, R24, R25, R30, R34, R37, R41, R44	R10, R21, R22, R36, R38
11	R1 to R6, R7, R12, R14, R15, R16, R17, R19	R8, R9, R11, R18, R30, R44	R10
12,13,14	R1 to R6, R7,R12, R17,R19,R27,R35,R39	R9, R11, R24, R34, R37, R41	R10,R21,R36,R38
17	R7,R12,R17,R27,R35,R39	R11,R18,R24,R30,R34, R37,R41	R10, R21,R36
18	R7, 12	R11,R18,R30	R10
19	R1 to R6, R12, R15	R8, R11, R18, R30	
20	R35	R34	
21,22,23	R1 to R6, R7, R12, R14, R15, R16, R17, R19, R27,R35, R39	R8, R9, R11, R18, R24,R30, R34, R37, R41, R44	R10, R21, R36, R38
24		R1 to R6, R7, R12, R14, R15, R16, R17, R19, R27,R35, R39	R8, R9,R10, R11, R18,R21, R24, R30,R34,R36,R37,R38,R41, R44
25	R2,R3,R5,R6,R7,R12, R14, R15,R16, R17,R19	R8,R9,R11,R18,R30, R44	R10
26	R27,R35,R39	R24,R34,R37,R41	R21,R36,R38
27	R7,R12,R27,R35,R39	R11,R18,R24,R30,R34,R37,R41	R10, R21,R36
28 29	R1 to R6, R7, R12, R14, R15, R16, R17, R19, R27, R28, R35, R39	R8, R9, R11, R18, R24, R25, R30, R34, R37, R41, R44	R10, R21, R22, R36, R38 R10
30, 31 33	R1 to R6, R7, R12, R14, R15, R16, R17, R19, R27, R28, R35, R39	R8, R9, R11, R18, R24, R25, R30, R34, R37, R41, R44	R10, R21, R22, R36, R38 R10
40	R8, R9, R11, R18, R24, R25, R30, R34, R37, R41, R44	R8, R9, R11, R18, R24, R25, R30, R34, R37, R41, R44	R10, R21, R22, R36, R38
41,42	R27, R35, R39	R24, R34, R39,R41	R21,R36

511

512 Level of exposure

513 The level of exposure (LE) is an indicator of the frequency with which exposure to the risk occurs.
 514 The level of exposure can be estimated according to the time spent in areas and/or tasks where the
 515 risk has been identified. Its meaning is shown in Table E.9-4.

516 **Table E.5-4 :Determination of the level of exposure**

LE	MEANING
1	Occasionally.
2	Sometimes during the working day and for short periods of time.
3	Several times during the working day for short periods of time.
4	Continuously. Several times during the working day for prolonged periods of time.

517 As can be seen from Table E.9-1, the values assigned are lower than those assigned for the
 518 objective hazard rating given that, if the risk situation is controlled, high exposure should not give
 519 rise to the same level of risk as a very deficient situation involving low exposure.
 520

521 Level of consequences

522 The consequences normally expected if the risk should occur will be taken into consideration. Four
 523 levels of consequences (LC) which categorise the personal harm which can be expected should the
 524 risk occur are established.

525 As can be seen from Table E.9-5, the numerical value assigned to the consequences is much higher
 526 than those of the objective hazard rating and level of exposure, given that the consequences should
 527 always be much more heavily weighted in the risk assessment.

528 **Table E.5-5 : Determination of the level of consequences**

LC	MEANING
100	One or more fatalities
60	Serious injuries which may be irreversible
25	Normally reversible injuries
10	Minor injuries

529 Level of risk

530 All the steps carried out up to this point lead to the determination of the level of risk which is
 531 obtained by multiplying the objective hazard rating by the level of exposure and the level of
 532 consequences (Table E.9-6).

533

Table E.5-6: Determination of the level of risk

		(OHR x LE)			
		2 - 4	6 - 8	10 - 20	24 - 40
(LC)	10	20 – 40	60 – 80	100 – 200	240 - 400
	25	50 - 100	150 – 200	250 – 500	600 - 1000
	60	120 – 240	360 – 480	600 – 1200	1440 - 2400
	100	200 – 400	600 – 800	1000 – 2000	2400 - 4000

534

535 Table E.9-7 gives the meanings of the four levels of risk obtained.

536

Table E.5-7 : Meanings of the various levels of risk

LEVEL OF RISK	LR	MEANING
1	40 – 20	Improve as much as possible. Periodic checks are required to ensure that the effectiveness of current measures is maintained.
2	120 - 50	Establish measures to reduce the risk and introduce these within a specified period
3	500 - 150	Correct and adopt short-term control measures
4	4000 - 600	Situation requiring urgent correction

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