



TECHNICAL GUIDANCE DOCUMENT FOR PREPARING THE CHEMICAL SAFETY ASSESSMENT

Chapter R.17

Exposure assessment of substances in articles

**“Technical Guidance Documents in support of the New EU Chemicals Legislation (REACH) –
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1 **R.17 EXPOSURE ASSESSMENT OF SUBSTANCES IN ARTICLES**

2 **R.17.1 Introduction**

3 **R.17.1.1 Aim**

4 This section shows how to assess exposure to substances in articles for man and environment
5 (produced or imported), either as part of the life-cycle of a *substance* to be registered, or as part of a
6 registration for articles, in case *substances in articles* are intended to be released, or when the
7 Agency has grounds for suspecting that substances are released and this poses a risk. See the
8 guidance on registration of substances in articles (RIP3.8) for details and definitions.

9 **R.17.1.2 General work flow**

- 10 1. Consider the emission pathways (section R.17.1.3) and exposure pathways of the
11 substances in articles (section R.17.1.4). In general, the use and service-life life stages are
12 applicable.
- 13 2. Document the available information on the amount of articles and incorporated substances is
14 manufactured, imported or used. Consider that articles that are produced, and emissions of
15 substances from these articles, can potentially accumulate in the technosphere over the
16 service life of the article (section R.17.4.2). Consider the current measures to control the risk
17 of substances in articles.
- 18 3. Consider an exposure estimation strategy (section R.17.2). Estimate exposure of humans
19 (section R.17.3) and release to the environment (R.17.4) using the appropriate tools. The
20 exposure estimation categories described in Part D can be used for a Tier 1 exposure
21 estimate. For human exposure, use can be made of the preparation and article categories (see
22 Part D and Chapter R.15). For environmental exposure, use can be made of the
23 environmental release categories (ERCs, see Part D and Chapter R.16).
- 24 4. Environmental Tier 1 release estimates, whether derived from applying the ERCs or the
25 equations in section R.17.4, are used as input into calculating predicted environmental
26 concentrations (PECs). Tier 1 release estimates for diffuse emissions from articles during
27 service life are considered on a regional scale.
- 28 5. Based on the risk characterisation (section R.17.1.5), define the operational conditions and
29 RMMs that ensure control of risks for release of substances from articles for man or
30 environment for inclusion in the exposure scenario. This could include product integrated
31 RMMs that influence release or migration from the article, or recommendation of specific
32 concentration or migration limits.

33 **R.17.1.3 Emission pathways**

34 Emissions can in principle come from virtually any article. Emissions can be classified into four
35 different groups:

36

37

- 38 • Release into surrounding air (by evaporation)
- 39 • Release into saliva or surrounding water (leaching)
- 40 • Release into surrounding solid material or skin (by diffusion)
- 41 • Release in the form of material particles to various surroundings (e.g. due to wear and tear)

42 In the first three groups, the chemical is emitted in molecular form. In the fourth group the chemical
43 is emitted in the form of particles of material. The particles may be assumed to have the same
44 composition as the original material.

45 **R.17.1.4 Exposure pathways**

46 Exposure assessment for substances in articles need to take into account that certain articles are
47 associated with specific exposure pathways due to their expected use or reasonable foreseeable
48 misuse, such as chewing (pens), mouth contact (textiles, objects put in the mouth) or accidental
49 ingestion.

50 The likelihood of exposure for each of the relevant pathways for exposure to substances in articles
51 needs to be established. The following questions will be helpful in determining the relevant human
52 exposure pathways.

- 53 • Can the article be put in the mouth unintentionally (e.g. chewing) or is it intended to be?
- 54 • Is there skin contact with the article, e.g. jewellery, textiles, straps, belts, shoes etc.
- 55 • Can the article or parts or particles of it be ingested?
- 56 • Can substances in the article evaporate and thus be inhaled (based on default or measured
57 release rates)?
- 58 • Can the article release the substance due to abrasion, drilling, sawing, sanding, handling,
59 heating etc. and thus lead to exposure via dust or fumes?

60 It is assumed that eye contact with substances in articles is generally not a relevant exposure
61 pathway; however specific eye-irritants may need attention if that substance would be intentionally
62 released from the article.

63 The following questions will be helpful in determining the relevant environmental exposure
64 pathways during use and handling of the article:

- 65 • Is the substance released intentionally from the article?
- 66 • Is evaporation of substances from the article matrix likely?
- 67 • Is leaching to (ground)water and redistribution to soil/sediment possible?
- 68 • Is particle abrasion or loss of particles likely at any stage?
- 69 • How are articles handled in the waste stage and does this lead to releases?

70 **R.17.1.5 Demonstration of control of risks**

71 The specifications for control of risks of substances in articles as outcome of the CSA can be
72 expressed as exposure by a pathway (or any combination of pathways) that is below the DNEL or
73 PNEC. The safety of an article for screening purposes can be demonstrated with worst case
74 assumptions. For oral exposure, it could be assumed that all of the substance contained in the article
75 is released instantaneously and is available for oral exposure. If this does not lead to exceeding the
76 DNEL for oral exposure, control of risks can be assumed.

77 Another approach for human exposure assessment of articles is to derive specific concentration
78 limits for oral exposure (CL, Van Engelen et al., 2006), based on the DNEL. By re-arranging the
79 Tier 1 equations for oral exposure, it is then possible to calculate the content limit as the

80 concentration (mg/kg article material) in the article, assuming the entire article is swallowed
81 (mostly applicable to small articles easily swallowed):

$$82 \quad CL(\text{mg/kg article}) = \frac{\text{DNEL} \cdot \text{BW}}{A_{\text{tot}} \cdot \nu}$$

83

Parameter	Description	Unit	Source
DNEL	Derived No-Effect Level	[mg.kg bw ⁻¹ .d ⁻¹]	Hazard assessment
BW	Body weight	[kg]	
A _{tot}	Total article weight (all ingested)	[kg]	
ν	use frequency = mean number of (ingestion) events per day	[d ⁻¹]	

84

85 In analogy to methodologies used at EFSA for calculating release limits for food contact materials
86 ,it is also possible to calculate specific migration limits (SML) for oral exposure in mg/kg article
87 material. The SML is based on the assumption that a maximum amount of article is ingested per day
88 (*A_{ingested}*) and all of the substance in the ingested amount of article is available for oral uptake.

89 The SML that does not lead to exceeding the DNEL is then calculated as:

$$90 \quad \text{SML}(\text{mg/kg article}) = \frac{\text{DNEL} \cdot \text{BW}}{A_{\text{ingested}} \cdot \nu}$$

91

Parameter	Description	Unit	Source
DNEL	Derived No-Effect Level	[mg.kg bw ⁻¹ .d ⁻¹]	Hazard assessment
BW	Body weight	[kg]	
A _{ingested}	Article weight that is ingested per event	[kg]	
ν	use frequency = mean number of (ingestion) events per day	[d ⁻¹]	

92 Migration limits can also be expressed on an area basis [mg.kg⁻¹.cm⁻²]. If risks are not controlled,
93 product-integrated risk management measures or other RMMs can be implemented to reduce the
94 substance losses from the articles to humans or the environment. See Part D and Chapter R.13 for
95 more information on applying RMMs.

96 R.17.2 Exposure assessment steps

97 A sequence of exposure assessment steps is given below. Entry and exit is possible at any step,
98 assuming that the exposure assessment is embedded in the usual steps of the chemical safety
99 assessment. After a specific step, the use is either safe (exposure below DNEL or PNEC or below
100 migration limits), or not. If not, additional refinement of the CSA is needed by either working on
101 the exposure estimation, introducing (further) risk management measures or generation of
102 additional hazard data.

103 Step 1: Tier 1 exposure estimation

104 In this step, the chemical composition of the article is used to test if the overall amount present in
105 the article, with default worst case assumptions, could lead to exceeding the DNEL or PNEC or not.
106 This is detailed in section R.17.3.

107 If a complete (instantaneous) emission of all of the substance of interest contained in an article is
108 below the relevant DNEL or PNEC, or worst case emission assumptions will not lead to exceeding
109 the DNEL or PNEC, no additional assessment is necessary for direct human exposure. Indirect
110 exposure via (release to) the environment could be relevant for humans and cannot *a priori* be
111 disregarded without some form of quantification.

112 Tier 1 screening equations are available for environmental exposure, inhalation exposure, skin
113 exposure or systemic exposure from multiple pathways. The exposure assessment should accurately
114 reflect article handling and exposure (contact time, frequency of contact, exposure pathways etc.).

115 Depending on the use and physicochemical properties of the substance in the article, the exposure
116 assessment should reflect the relevant release processes:

- 117 • For environmental exposure, the assessment should focus on release to air, water or
118 soil/sediment by evaporation, leaching into (pore) water or particle abrasion.
- 119 • For human exposure, the release of substances from the article matrix into the relevant contact
120 media such as air, (drinking) water, fluid (saliva or gastro-intestinal fluids), dust or skin (dermal
121 exposure) should be assessed, and if relevant, reflected in the exposure scenario.

122 When using calculations based on Article Categories (see Appendix D-1), the assumptions of any
123 defaults in a category must be checked against the exposure pathways and environmental release
124 patterns for that particular article category, and adapted if needed.

125 Step 2: Refinement of the Tier 1 exposure assessment, e.g. use measured release data

126 The Tier 1 assessment can be improved by refining the assumptions. This can be done, e.g. by using
127 more elaborate models to estimate the release or uptake rate of substances, as discussed here in
128 R.17.4, or by suitable measurements

129 Measurements on leaching, release or exposure concentrations can be used as input into the
130 assessment. The release data for the relevant exposure pathway can be compared to the DNEL for
131 short- or long term exposure or to the PNECs for environmental compartments.

- 132 • The environmental exposure assessment should focus on release to air, water or soil/sediment
133 by evaporation, leaching into (pore) water or particle abrasion. The release of substances into
134 environmental media can be detailed, e.g. by measured leaching rates etc.
- 135 • For human exposure, the release of substances from the article matrix into the relevant contact
136 media such as air, (drinking) water, fluid (saliva or gastro-intestinal fluids) or skin (dermal
137 exposure) could be measured with standardized test methods (using the test methods of Annex
138 ta1). It should be established whether substances migrate from the matrix in the mouth or (also)
139 in the gastro-intestinal tract.

140 Step 3: Higher tier exposure assessment

141 If the previous steps still cannot demonstrate control of risks, higher tier assessment can be
142 considered. Higher tier, specific exposure models can be used or additional release or exposure
143 information can be collected or measured. Especially data or models for release from a matrix could
144 be used to further refine the assessment. Several tools and information sources are available for this,

145 see Appendix R.17-1. Collecting information on release rates from articles). Higher tier models for
146 consumer exposure assessment are discussed in Chapter R.15.5.

147 **R.17.3 Release and exposure estimation for humans**

148 The safety of an article for screening purposes can be demonstrated from the composition of the
149 article. The worst case assumption is that all of the substance contained in the article is released
150 instantaneously and is available for inhalation, dermal or oral uptake. If the article is a composite,
151 the relevant part of the article is used for article weight. The sections below briefly state the
152 assumptions and refer back to Chapter R.15 on consumer exposure assessment.

153 **R.17.3.1 Inhalation**

154 **R.17.3.1.1 Volatile substances**

155 Substances can be released from articles by evaporation, depending on the physicochemical
156 properties of that substance and the properties of the matrix that influence migration out of the
157 article into air or water. A tier 1 screening approach assumes that 100% of the substance of the
158 product will be released at once to the room and there is no ventilation. Furthermore, in a worst case
159 model, it is assumed that the event duration is 24 hours.

- 160 • Use the Tier 1 inhalation model (Section R.15.4.1.1).

161 **R.17.3.1.2 Inhalation of particles or dust**

162 The substance in articles may become available for inhalation due to rubbing or while handling or
163 working with the article (e.g., building materials, hobby materials etc.) due to sanding, drilling,
164 heating of metals (metal fume particles with very small diameter) etc. The resulting dust can be
165 inhaled.

- 166 • Use the Tier 1 inhalation model (Section R.15.4.1.1), with a conservative assumption on the
167 inhalable and/or respirable fraction. The non-respirable fraction can be swallowed and oral
168 exposure may also need to be considered.

169 The inhaled amount depends on the particle size distribution. In general, we can assume that
170 particles with a diameter below 15 μm will be taken up, although different defaults are used by
171 different exposure models. This is based on the notion that particles between 5 and 15 μm are taken
172 up orally and particles below 5 μm reach the alveoli.

173 **R.17.3.2 Dermal contact**

174 Many tools and machinery are handled leading to skin contact. Other classes of articles are in
175 contact with some part of the skin, especially clothing, foot wear, jewellery etc. Dermal contact is
176 also very relevant for sensitizing chemicals. In general, a distinction can be made between short-
177 term exposure, e.g. handling tools or machinery, and long-term exposure; for instance shoes,
178 textiles, jewellery, straps, etc.

- 179 • Use the Tier 1 dermal exposure model B: a non-volatile substance migrating from an article
180 (Section R.15.4.1.2).

181 More detailed dermal exposure models are discussed in section R.15.5.

182 **R.17.3.3 Ingestion**

183 **R.17.3.3.1 Ingestion of product or article**

184 Articles, parts or particles from articles can be ingested. In many cases, depending on the article
185 category, ingestion of article parts can be expected and is an element of reasonable foreseeable
186 misuse. A well known example is chewing on articles such as pens or other household materials, or
187 ingestion of small articles by children.

- 188 • Use the Tier 1 oral exposure model A: Unintentional swallowing during normal use (Section
189 R.15.4.1.3). If the article is diluted before use, an additional dilution term can be added to the
190 equation above.

191 **R.17.3.3.2 Migration from article**

192 For articles that may be taken into the mouth or sucked on (mouthing) as part of reasonable
193 foreseeable misuse, substances can migrate into saliva or (through it) to skin. This could be limited
194 to a few classes of articles.

- 195 • For a screening assumption on migration, also use the Tier 1 oral exposure model A:
196 Unintentional swallowing during normal use (Section R.15.4.1.3).

197 In a higher tier model, the release rate of the substance from a product can be measured and the
198 exposure time assessed to obtain a more reliable estimate of substance released from the article. The
199 amount of ingested substance can then be calculated. Higher tier migration models for oral contact
200 are discussed in section R.15.5.

201 **R.17.3.4 Eye contact**

202 It is assumed that eye contact is usually not a relevant exposure pathway for articles, with a few
203 exceptions, e.g. contact lenses. In those cases, consider using the dermal models (see previous
204 R.17.3.1.2).

205 **R.17.4 Tier 1 Exposure estimation for the environment**

206 **R.17.4.1 General considerations**

207 A difference with environmental exposure to substances in articles is that the controlling weight or
208 shape is not the weight or shape of a single object handled, chewed on or ingested, but the aggregate
209 emission from the total weight or area of the articles in which the substance is contained. It is
210 assumed that the releases of substance during manufacture of the article are covered by a regular
211 CSA if the substance is manufactured in the EU.

212 To calculate exposure for the environment, the estimated loading of the environment is calculated
213 from release rates and the tonnage of the substance contained in the articles. Subsequently, the
214 calculated or measured overall emission is treated as any other environmental emission in the
215 current exposure assessment. They are considered diffuse emissions and need to be calculated for
216 the scale. The emissions during service-life usually cause exposure on a “regional” scale. In some
217 cases, however, local exposure scenarios should also be considered. Examples of local scenarios are
218 e.g. wood preservatives, leaching substances from construction materials etc.

219 Emission is greatly influenced by the total quantity of article. If an article has been in use for a
 220 prolonged period of time, with a relatively constant consumption (with regard to volumes and areas
 221 of use), the maximum cumulative quantity has had time to become established. At this stage, the
 222 annual quantity removed (by waste incineration, degradation etc.) is just as high as the quantity
 223 added annually. Then the chemical flow in society has reached an overall equilibrium (“steady
 224 state”). The cumulative quantity can be estimated in a simplified manner by multiplying the
 225 quantity added by the residence time of the chemical in years. Release into the environment (air,
 226 water, soil and indirectly, sediment) is calculated from the emission rate, the weight of the article(s)
 227 and the service life of the article.

228 A usual Tier 1 screening taking the service life of the article into account is to assume a constant
 229 release rate over time, called ‘emission factor’ [%] if the surface area is not the controlling factor
 230 for release:

$$R_{tot_comp} = F_{service\ life_comp} \cdot A_{tot} \cdot F_{c_art} \cdot T_{SL_article} \quad \text{Equation 17-1}$$

231 with

232
 233 R_{tot_comp} = annual total release of the substance to a certain environmental compartment
 234 (comp) over the service life of the products at steady state [kg/yr]
 235 $F_{service\ life_comp}$ = emission factor to a certain environmental compartment over service life of the
 236 articles [%] (estimated or measured)
 237 A_{tot} = yearly total input of the the articles [kg/yr]
 238 F_{c_art} = weight fraction of substance in article [-]
 239 $T_{SL_article}$ = service life of articles [yr]
 240

241 This calculation can be repeated for each relevant environmental compartment. Note that the
 242 emission factor to each environmental compartment can be different depending on the properties of
 243 the substance and the article matrix. Losses of substances to loss of particles (abrasion, wear and
 244 tear) can also be calculated in this way by defining a) an emission factor from the particles, and a
 245 separate particle loss fraction in addition [%].

246 An alternative method of estimating the emission from articles over their service life is to assume
 247 that the emission is directly proportional to the surface area of the objects exposed to water
 248 (leaching) or air (volatilisation). This approach needs area emission factors (F_{area} [$mg \cdot m^{-2} \cdot year^{-1}$]). If
 249 such emission factor are known or can be estimated for a substance in an article, the emissions of
 250 the substance can be estimated as follows:

$$R_{tot_Subst_comp} = F_{area, comp} \times Area_{article} \times T_{sl_article} \quad \text{Equation 17-2}$$

251 with

252 $R_{tot_Subst_comp}$ = annual total release of the substance to a certain environmental compartment
 253 (comp) over the service life of the products at steady state [kg.yr-1]
 254 $F_{area, comp}$ = annual emission factor to an environmental compartment (comp) on an article-
 255 area basis [$kg \cdot m^{-2} \cdot year^{-1}$]
 256 $Area_{article}$ = annual emitting surface area [$m^2 \cdot yr^{-1}$]
 257 $T_{SL_article}$ = service life of articles [yr]

258 The relevant ERCs can be adapted for service life by applying equations Equation 17-1 or Equation
 259 17-2 to the emission factors in the ERCs

260 More detailed calculations of emissions from articles can be performed by using the equations in
261 the next sections. This process is simplified by using the ERCs as described in section R.16.2 for
262 the relevant process and article category that is applicable to the articles.

263 The steps are explained in more detail in the next sections:

- 264 1. Estimate the service-life of the article.
- 265 2. Consider the emission type (molecular and/or particulate).
- 266 3. Estimate emission factors for the substance from the actual material (e.g. fraction/tonne or
267 mg.m⁻² surface area). If emission data are missing:
 - 268 - Compare with similar articles described in ESD's or other sources;
 - 269 - Search for data in the literature;
 - 270 - Use a worst-case assumption or if necessary perform an emission study, leaching study
271 etc..
- 272 4. Calculate of the total releases of substance from articles at steady state
- 273 5. Calculate the regional releases representing a densely populated area.

274 **R.17.4.2 Detailed release estimation for service-life**

275 **R.17.4.2.1 Considerations**

276 Although not required by the legislation, the M/I or article producer may wish to know what his
277 market volume contributes to the overall release and whether there is any probability that a
278 substance evaluation under REACH may conclude that additional risk management is needed.
279 Hence the manufacturer may wish to use the total EU market volume for his substance in his
280 calculations.

281 Although not explicitly required, the M/I or article producer may wish to know whether his market
282 volume stocks up a base-line release from articles accumulated in the technosphere over the past.
283 He can take account of this in using the default release rates referring to the whole service life as an
284 annual release rate (see "steady state" concept in section R.17.4.2.6).

285 **R.17.4.2.2 Input data**

286 Substance emissions during service-life are assessed at regional level. It is assumed that the
287 emissions homogenously disperse in the environment over time. Hence the manufacturer needs
288 different types of information:

- 289 1. Article types in which his substance is used and
- 290 2. the average service life of these products.
- 291 3. The fraction of the marketed volume used in certain product types.
- 292 4. An emission factor (release rate) per year. In a tier 1 assessment, a default emission factor can
293 be used based on the ERCs (see Section R.16.2). Specific information can be used to substitute
294 the defaults, e.g. based on models (for example for packaging materials) or based on testing.

295 **R.17.4.2.3 Estimate the service life of the article**

296 Service life is the use of articles or the polymer matrix of a preparation (paints, adhesives)
297 containing the substance over a period > 1 year. Such activities include for example wearing and

298 maintenance of textiles, housing, using and maintenance of vehicles, use and maintenance of sport
299 articles.

300 A list of examples for service life spans and release factors taken from the emission scenario
301 document on plastic additives is presented in Table R.17.1.

302 **Table R.17.1: Example of service life and release factors (per year) for polymer articles**

Article type	Typical service life time	Release factor plasticizer, medium volatility	Release factor for anorganic flame retardant or stabiliser
Packaging materials, articles used in agriculture	1		
Sports articles, plastic used in electric devices	2 to 5 years		
Furniture, household appliances (e.g. refrigerator)	5 to 10 years		0.01% per year
Plastic used in electronic devices, cars, construction materials	10 to 20 years	0.16% per year	
Tyres	5 years		

303 The service life of an article can be defined as the average lifetime of the article. If a significant
304 proportion of an article/material/substance is re-used or recycled leading to a second service life this
305 should be considered in the exposure assessment. Depending on the re-use/recycle pattern this can
306 be handled in different ways:

- 307 • if the recycling of an article leads to a second service life with the same or a similar use as the
308 first service life this can be accounted for by adequately prolonging the first service life;
- 309 • if the recycling of an article leads to a second service life different from the first service life,
310 emissions from both service lives are calculated separately;
- 311 • if the substance/material is recovered and used as raw material for production of new articles
312 this amount should be added to the appropriate life-cycle stage (formulation,
313 industrial/professional use), if not already accounted for.

314 **R.17.4.2.4 Consider the emission type (molecular and/or particulate)**

315 There are several mechanisms for diffuse emission such as evaporation, leaching, corrosion,
316 abrasion and weathering effects. An additional release route that in some cases is of importance is
317 when a substance diffuses from one material into another (e.g. from glue material into construction
318 material). Substances that are slowly emitted from long-life materials are often characterised by
319 inherent properties such as low water solubility and low vapour pressure (e.g. semi-volatile
320 substances). Particulate emissions will have different fate and behaviour properties compared to
321 molecular emissions e.g. lower bioavailability and longer persistence. However, in the absence of
322 more detailed data concerning adsorption/bioavailability/persistence, the substance content in small
323 particles can be handled as if it was distributed in molecular form.

324 For the molecular emission of additives from long-life materials, the emission can normally be
325 expected to be highest in the beginning of the use period (due to diffusion mechanisms). The
326 opposite situation occurs for solid metal products where the particle emission can be expected to be
327 highest at the end of the use period. It is necessary to be aware that the emission factors are
328 normally an average for the whole service life.

329 **R.17.4.2.5 Emission Factors**

330 The emission from articles can be assumed to be proportional to the surface area. It is, however, not
331 always possible to estimate this area. Weight based emission factors are then used (i.e.
332 fraction.tonne⁻¹ or kg.m⁻² surface area).

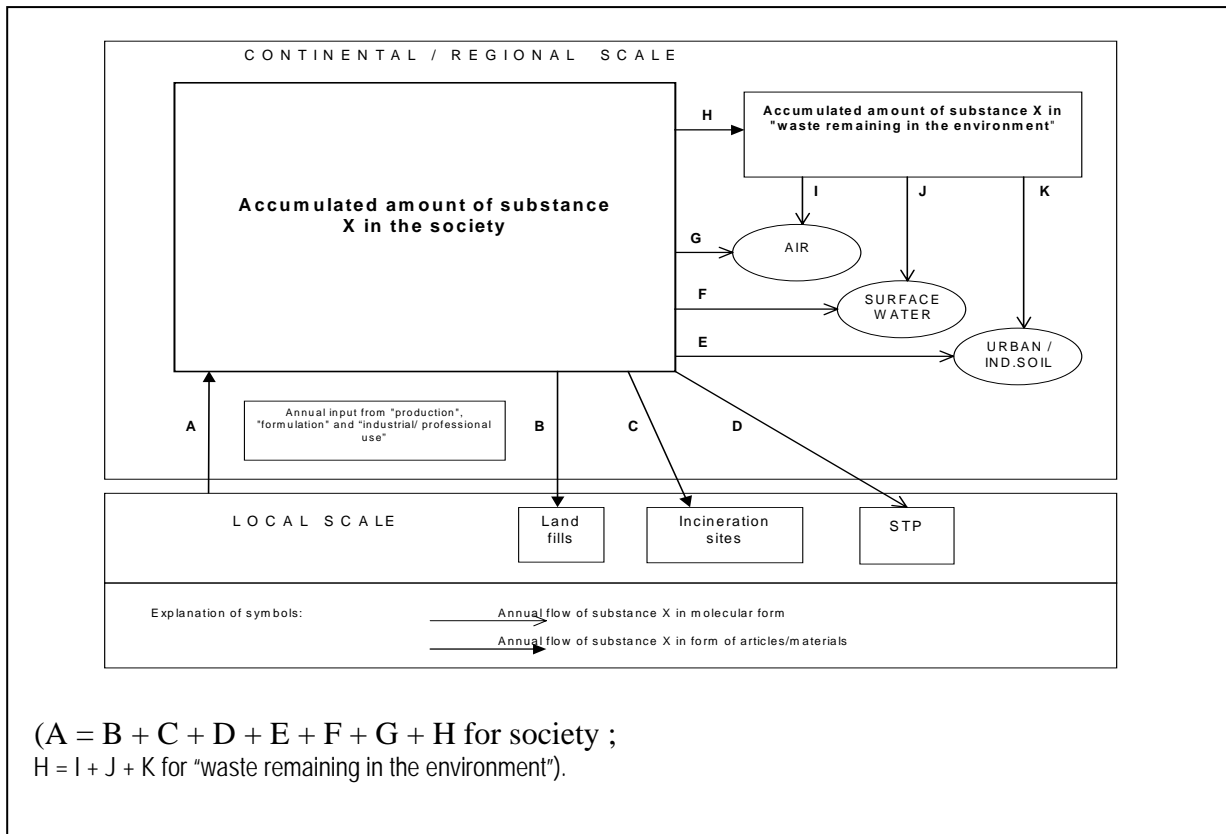
333 The emission factors are driven by the following main characteristics of the substance, the article
334 and the environment:

- 335 • geometric form of the material determining the content-to-surface-ratio
- 336 • the chemical-physical properties of the substance (e.g. water solubility, vapour pressure, form of
337 the molecular
- 338 • the environment of use (weathering, eroding forces, heat)
- 339 • the interaction between the matrix and the substance

340 In particular the geometric form of the finished material and the interaction between substance and
341 matrix is difficult to predict for the manufacturer of the substance, without having detailed
342 knowledge on the type of article. Here he has to rely on conservative default assumptions in the
343 ERCs (see Section R.16.2) or emission scenario documents as for example available for plastic
344 materials.

345 **R.17.4.2.6 Calculate of the total releases of substance**

346 The emissions from long-life articles can be expected to be highest at steady state (i.e. when the
347 flow of an article into society equals the outflow, see Figure R.17-1.



348 **Figure R.17-1 Emissions from long-life articles at Steady state**

349

350 Releases from waste remaining in the environment (H) will also contribute to the continental and
 351 regional releases. Further details on emissions from the waste stage are given in Chapter R.18.

352

353 Assuming constant annual input of the substance and a constant emission factor the equation for the
 354 releases to a specific compartment and for the total of all compartments can be written as:

$$RELEASE_{tot_steadystate_{i,j,k}} = F_{i,j} \cdot Q_{tot_accum_steadystate_k} \quad \text{Equation 17-3}$$

355 and:

$$RELEASE_{tot_steadystate_{i,total,k}} = F_{i,total} \cdot Q_{tot_accum_steadystate_k} \quad \text{Equation 17-4}$$

356 where the amount accumulated in product k in the society at the end of service life (steady state) can
 357 be calculated as:

$$Q_{tot_accum_steadystate}_k = Q_{tot}_k \cdot \sum_{y=1}^{T_{service}_k} (1 - F_{i,total})^{y-1} \quad \text{Equation 17-5}$$

358

359 In situations where the emission factor is low ($< 1\% \cdot yr^{-1}$) and the service life of the product is not
 360 very long, the emissions and accumulation at steady state (eq. 17.7-9) can be simplified as:

$$RELEASE_{tot_steadystate}_{i,j,k} = F_{i,j} \cdot Q_{tot}_k \cdot T_{service}_k \quad \text{Equation 17-6}$$

361

$$RELEASE_{tot_steadystate}_{i,total,k} = F_{i,total} \cdot Q_{tot}_k \cdot T_{service}_k \quad \text{Equation 17-7}$$

362

$$Q_{tot_accum_steadystate}_k = Q_{tot}_k \cdot T_{service}_k \quad \text{Equation 17-8}$$

363 Explanation of symbols

$F_{i,j}$	Fraction of tonnage released per year (emission factor) during life-cycle stage i (service life) to compartment j	[-]	data set 1)
$F_{i,total}$	Fraction of tonnage released per year (emission factor) during life-cycle stage i (service life) to all relevant compartments	[-]	data set 2)
$RELEASE_{tot_steadystate}_{i,j,k}$	Annual total release to compartment j at steady state for product k	[tonnes · yr ⁻¹]	
$RELEASE_{tot_steadystate}_{i,total,k}$	Annual total releases to all relevant compartments at steady state for product k	[tonnes · yr ⁻¹]	
Q_{tot}_k	Annual input of the substance in product k	[tonnes · yr ⁻¹]	data set
$Q_{tot_accum_steadystate}_k$	Total quantity of the substance accumulated in product k at steady state	[tonnes]	
$T_{service}_k$	Service life of product k	[yr]	data set

364

- 1)
2)
- Alternatively use Equation 17-12
Alternatively use Equation R.16-18

365

366 The annual total amount that will end up as waste from product k at the end of service life at steady
 367 state (b+c+h in Figure R.17-1) can be written as (assuming no degradation within the article):

$$Q_{WASTE_{tot_steadystate}_k} = Q_{tot}_k - RELEASE_{tot_steadystate}_{i,total,k} \quad \text{Equation 17-9}$$

368 Explanation of symbols

QWASTE _{tot} _steady state _k	Total quantity of the substance in product k ending up as waste at steady state	[tonnes · yr ⁻¹]	
Q _{tot k}	Annual input of the substance in product k	[tonnes · yr ⁻¹]	data set
RELEASE _{tot} _steady state _{i, total, k}	Annual total releases to all relevant compartments at steady state for product k	[tonnes · yr ⁻¹]	eq. (8)

369 **R.17.4.2.7 Calculate the regional releases**

370 Using a 10% default the annual regional release from article k to compartment j and for the total of
371 all compartments can be calculated as:

$$RELEASE_{reg_steadystate_{i,j,k}} = RELEASE_{tot_steadystate_{i,j,k}} \cdot 0.1 \quad \text{Equation 17-10}$$

372 and:
373

$$RELEASE_{reg_steadystate_{i,total,k}} = RELEASE_{tot_steadystate_{i,total,k}} \cdot 0.1 \quad \text{Equation 17-11}$$

374 Explanation of symbols

RELEASE _{reg} _steady state _{i,j,k}	Annual regional release to compartment j at steady state for product k	[tonnes · yr ⁻¹]	
RELEASE _{reg} _steady state _{i, total, k}	Annual regional release to all relevant compartments at steady state for product k	[tonnes · yr ⁻¹]	
RELEASE _{tot} _steady state _{i,j,k}	Annual total release to compartment j at steady state for product k	[tonnes · yr ⁻¹]	Equation 17-6
RELEASE _{tot} _steady state _{i, total, k}	Annual total releases to all relevant compartments at steady state for product k	[tonnes · yr ⁻¹]	Equation 17-4 Equation 17-7

375 These regional diffuse releases are then added to the regional emissions calculated from non-diffuse
376 emissions (E_{regionalj}; -

377 If an emission factor is available as release per surface area, it can be converted to a product
378 specific “fraction of tonnage released” (F_{i,j} and F_{i,total}):

$$F_{i,j} \text{ (product specific)} = \frac{\text{EMISSIONarea}_{i,j,k} * 1000}{\text{THICK}_k * \text{CONC}_k} \quad \text{Equation 17-12}$$

379 and:

$$F_{i,\text{total}} \text{ (product specific)} = \frac{\text{EMISSIONarea}_{i,\text{total},k} * 1000}{\text{THICK}_k * \text{CONC}_k} \quad \text{Equation 17-13}$$

380 Explanation of symbols

$F_{i,j}$	Fraction of tonnage released per year (emission factor) during life		
	cycle stage i (service life) to compartment j from product k	$[\text{yr}^{-1}]$	
$F_{i,\text{total}}$	Fraction of tonnage released per year (emission factor) during life		
	cycle stage i (service life) to all relevant compartments from product k	$[\text{yr}^{-1}]$	
CONC_k	Concentration of substance in product k	$[\text{kg} \cdot \text{dm}^{-3}]$	data set
$\text{EMISSIONarea}_{i,j,k}$	Annual amount of substance emitted per area from product k		
	to compartment j	$[\text{g} \cdot \text{m}^{-2} \cdot \text{yr}^{-1}]$	data set
$\text{EMISSIONarea}_{i,\text{total},k}$	Annual total of amount substance emitted per area from product k	$[\text{g} \cdot \text{m}^{-2} \cdot \text{yr}^{-1}]$	data set
THICK_k	Thickness of the emitting material in product k	$[\text{mm}]$	data set

381 If the area based emissions can be expected to decrease with decreasing concentration in the
 382 product the Equation 17-9-and Equation 17-10 above are used. If the emission is expected to be
 383 independent of the remaining amount of the substance in the product, e.g. corroding metals, the
 384 simplified Equation 17-12 and Equation 17-13 are used.

385 If the amount of a substance in use in the society has not reached steady state and the accumulation
 386 is still ongoing, the calculated PEC will represent a future situation. If this is the case this should be
 387 considered when comparing PEC with monitoring data.

388 Releases from articles will normally only contribute to the continental and regional releases. The
 389 emissions from indoor uses can be released to wastewater and therefore be regarded as a point
 390 source (stream D in Figure R.17-1). Also outdoor uses may cause releases to STP if the storm water
 391 system is connected to the STP. This has to be considered case by case. For the calculation of a
 392 local scenario the B-table in Annex I for Industry Category 5 Personal/domestic shall be used.

393 **R.17.5 Refined exposure estimation (step 2)**

394 **R.17.5.1 Release rates of substances from articles**

395 For more specific calculations, e.g. on losses during service life, it may be needed to calculate the
396 release rate of a substance from an article. The release rate may be constant, or change over time.
397 This depends on the function of the article and the properties of the substance and the article matrix
398 in which it is contained.

399 For screening purposes, simple worst-case assumptions may be sufficient. The article
400 producer/importer of articles that contain substances intended to be released should have more
401 detailed, relevant information on estimating the release rate and the total amount released from their
402 articles.

403 Two main possibilities are distinguished:

- 404 • The release is controlled by the user of the article (e.g., release of ink from a pen) and therefore
405 dependent on use frequency and use time per event. The release is constant over the time of use
406 to ensure its function.
- 407 • The release is controlled by the matrix of the article, e.g. scented objects. The release is
408 declining over time because the total amount of substance in the object declines over time
409 (usually approximated by first-order release kinetics).

410 The release rate of a substance from an article can be expressed on a weight basis (mg.kg⁻¹.d⁻¹) or
411 on a surface basis (mg.m⁻².d⁻¹), depending on the type of substance and use characteristics of the
412 object. Release rates can be

- 413 • Based on worst-case assumptions, e.g. all substance contained in the article is released (almost)
414 instantaneously, or released over a period of time representing the service-life, etc. This can be
415 useful for screening purposes.
- 416 • Modeled using appropriate software.
- 417 • Measured under the relevant conditions.

418 For some classes of articles, release rates are given in relevant OECD emission scenario documents
419 (e.g., on plastic additives; OECD 2004). Appendix R.17-1-lists references on collecting information
420 on release rates.

421 **R.17.6 Conclusions**

422 The proposed methodology assumes that it is possible to assign an article category that also defines
423 the uses of the article. A proposal for product use categories was done by ECETOC in the
424 ECETOC-TRA. However, no explicit exposure scenarios exist as yet for these categories. The
425 current methodology introduces a step-wise refinement of exposure assessment, where the safety of
426 articles can be estimated based on

- 427 a. Product composition data and Tier 1 exposure models
- 428 b. Refinement of release rates with more elaborate release modeling or measured release rates
- 429 c. Higher tier exposure assessment taking into account more complicated combinations of
430 exposure frequency, contact time, release rates etc.

431 **R.17.7 References**

- 432 Fischer, S (2006). Complementing Guideline for writing ESD's: The life-cycle step "Service-life". Draft document for
433 the OECD Task Force on Environmental Exposure Assessment, June 2006.
- 434 OECD (2004). Emission scenario document on plastics additives. Series on Emission Scenario Documents No. 3.
435 Environmental Health and Safety Publications, ENV/JM/MONO(2004)8 OECD.
- 436 Oomen AG, Rompelberg CJM, Bruil MA, Dobbe CJG, Pereboom DPKH, Sips AJAM. (2003). Development of an in
437 vitro digestion model for estimating the bioaccessibility of soil contaminants. Arch. Environ. Contam. Toxicol. 44:
438 281–287.
- 439 Petersen J.H., Trier X.T., Fabech B (2005). Mathematical modelling of migration: A suitable tool for the enforcement
440 authorities? Food Additives and Contaminants 22: 938–944.
- 441 Van Engelen et al. (2006). Chemicals in toys. A general methodology for assessment of chemical safety of toys with a
442 focus on elements. RIVM/SIR advisory report 0010278A02.

443 **APPENDIX R.17-1. COLLECTING INFORMATION ON RELEASE RATES FROM**
444 **ARTICLES**

445 **Available data**

446 Annex 7 of the final RIP3.8 report lists many sources of substances in articles. These sources should
447 be consulted for a specific type or class of articles. Another source for exposure estimation for
448 articles is the EIS-Chemrisk database (<http://web.jrc.ec.europa.eu/eis-chemrisks>). A registration is
449 required in order to use the database.

450 **Model estimations**

451 Specific migration estimation models exist, for instance for release of substances from plastic or
452 polymer products. An example of such models is the MigraLite software
453 (<http://www.specialchem4polymers.com/tc/migration-center/eu-recommended.aspx>). Migration
454 models can be very helpful in the context of risk assessment (Petersen et al., 2005).

455 **Testing methods**

456 Human exposure

457 Testing methods are available to determine the release from the article into water, saliva or gastric
458 fluid (physiology-based extraction test). These tests assume that the object is either put in the mouth
459 or is ingested. The most refined method is a simulation of the gastro-intestinal digestion by an in-
460 vitro digestion model (e.g., Oomen et al., 2003).

461 Van Engelen et al. (2006) list and discuss the different methods for testing of release rates and
462 bioavailability of substances in toys that are either put in the mouth or ingested.