Guidance on information requirements and chemical safety assessment

Chapter R.17: Estimation of exposure from articles

October 2012

(Version 1.1)

Guidance for the implementation of REACH

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Reference: ECHA-12-G-20-EN
Publ.date: October 2012
Language: EN

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PREFACE

This document describes the information requirements under REACH with regard to substance properties, exposure, use and risk management measures, and the chemical safety assessment. It is part of a series of guidance documents that are aimed to help all stakeholders with their preparation for fulfilling their obligations under the REACH regulation. These documents cover detailed guidance for a range of essential REACH processes as well as for some specific scientific and/or technical methods that industry or authorities need to make use of under REACH.

The guidance documents were drafted and discussed within the REACH Implementation Projects (RIPs) led by the European Commission services, involving stakeholders from Member States, industry and non-governmental organisations. These guidance documents can be obtained via the website of the European Chemicals Agency (http://echa.europa.eu/web/guest/support/guidance-on-reach-and-clp-implementation). Further guidance documents will be published on this website when they are finalised or updated.

This document relates to the REACH Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006[1] and its amendments as of 31 August 2011.

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[1] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006).

DOCUMENT HISTORY

Version 1	First edition	May 2008
Version 1.1.	Corrigendum: (i) Implementation of minor recommendations concerning nanomaterials from RIP-oN3 (also reviewed for updates necessary to replace references to DSD/DPD by CLP references, but none identified for need to change in this document) (ii) Further minor editorial changes	October 2012

Convention for citing the REACH regulation

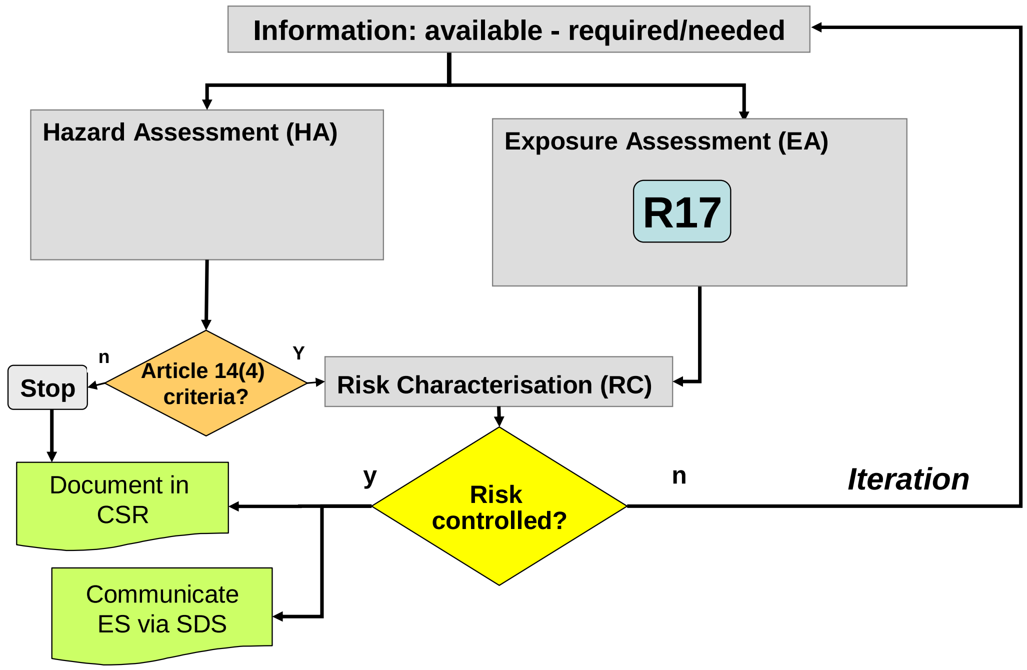
Where the REACH regulation is cited literally, this is indicated by text in italics between quotes.

Table of Terms and Abbreviations

See Chapter R.20

Pathfinder

The figure below indicates the location of Chapter R.17 within the Guidance Document



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R.17 EXPOSURE ASSESSMENT OF SUBSTANCES IN ARTICLES

R.17.1 Introduction

R.17.1.1 Aim

This section describes how to assess exposure to man and the environment from substances in articles which are produced or imported. Substances in articles can be assessed:

- as a part of the life-cycle stage of a *substance* to be registered (Article 6);
- as a part of a registration for substances in articles in case *substances in the article* are intended to be released (Article 7.1);
- when the Agency has grounds for suspecting that a substance in an article could be released and that this poses a risk (Article 7(5))See the Guidance on requirements for substances in articles for details and definitions.

R.17.1.2 General work flow

Exposure estimation for substances in articles is structured by a general workflow. This is meant to streamline the process but it can be adapted according to the available information or tools.

1. Document the available information on the quantity or number of articles that are produced, imported and used, and the quantity of the substances incorporated in the articles. Consider that articles that are produced, and emissions of substances from these articles, can potentially accumulate in society over the service life of the article (Section R.17.4.2). Consider the current measures to control the risk of substances in articles.

2. Consider the emission pathways (Section R.17.1.3) and exposure pathways of the substances in the articles (Section R.17.1.4). In general, the applicable life-cycle stages are ‘use’ and ‘service-life’. Service life relates to the use of an article containing the substance over a period of >1 year. Such activities include for example wear and maintenance of textiles, use and maintenance of vehicles or sport articles, etc.

3. Consider an exposure estimation strategy (Section R.17.2). Estimate exposure of humans (Section R.17.3) and release to the environment (Section R.17.4) using the appropriate equations and tools described in Chapters R.15 and R.16. The categories applied for description of uses can support tier 1 exposure estimates (see section D.4.4). For human exposure, use can be made of the product category and article categories (see Chapter R.12 and Chapter R.15). For environmental exposure, use can be made of the environmental release categories (ERCs, see Section D.4.4, Appendix D-3 and Chapter R.16).

4. Environmental Tier 1 release estimates, whether derived from applying the ERCs or the equations in Section R.17.4, are used as input into calculating predicted environmental concentrations (PECs), as described in Chapter R.16, using the appropriate tools (see Part D.5.4 and D.5.5). Tier 1 release estimates for diffuse emissions from articles during service life are considered on a regional scale.

5. Based on the risk characterisation (Section R.17.1.5), define the operational conditions (OC) and risk management measures (RMM) that ensure control of risks for release of substances from articles for man or environment for inclusion in the exposure scenario. This could

include product integrated RMM that influence release or migration from the article, or recommendation of specific concentration or migration limits.

R.17.1.3 Emission pathways

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

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

In the first three groups, the substance is emitted in molecular form. In the fourth group the substance is emitted in the form of particles of material. It is assumed that the particles have the same composition as the original material.

R.17.1.4 Exposure pathways

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

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

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

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

For the environment, the following questions will be helpful in determining the relevant environmental exposure pathways during use and handling of the article:

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

R.17.1.5 Demonstration of control of risks

The specifications for control of risks from substances in articles as outcome of the CSA can be expressed as exposure by a pathway (or any combination of pathways) that is below the DNEL or PNEC, see Part E for details on risk characterisation.

The safety of an article for screening purposes can be demonstrated with worst case assumptions. For human exposure estimation, e.g. for oral exposure, it could be assumed that all of the substance contained in the article is released instantaneously and is available for oral exposure. If this does not lead to exceeding the DNEL for oral exposure, control of risks can be assumed.

Another approach for human exposure estimation of articles is to derive specific concentration limits (CL) for oral exposure (Van Engelen et al., 2006), based on the DNEL. By re-arranging the Tier 1 equations for oral exposure, it is possible to calculate the content limit as the concentration (mg/kg article material) in the article, assuming the entire article is swallowed (mostly applicable to small articles easily swallowed):

$$\mathrm{CL(mg/kg\,article)} = \frac{\mathrm{DNEL} \cdot \mathrm{BW}}{\mathrm{A_{tot}} \cdot \nu}$$

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}]	

The body weight used should reflect the body weight of the population at risk, e.g. when assessing toys used by children. For further information on body weights, see Section R.15.7.

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

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

$$\mathrm{SML(mg/kg\,article)} = \frac{\mathrm{DNEL} \cdot \mathrm{BW}}{\mathrm{A_{ingested}} \cdot \nu}$$

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}]	

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

R.17.2 General considerations for exposure estimation

A sequence of exposure estimation steps is given below. Entry and exit is possible at any step, assuming that the exposure estimation is embedded in the usual steps of the chemical safety assessment. After a specific step, the use is either safe (exposure below DNEL or PNEC or below migration limits), or not. If not, additional refinement of the CSA is needed by either working on the exposure estimation or collecting measured exposure data, introducing (further) risk management measures or generating additional hazard data. If measured data of good quality are available, they can be used as input for model calculations or to override default model values at all steps and at all tiers. Please note that this tool has not been validated for use with nanomaterials (NMs). If the output of the model is used to estimate exposure for NMs, this should preferably be supported by measured data. There should be a clear description in the CSR of the uncertainties associated with the estimated values and the consequences for the risk characterisation.

Step 1: Tier 1 exposure estimation

In this step, the chemical composition of the article is used to assess whether the overall amount present in the article, with default worst case assumptions, can lead to exceeding the DNEL or PNEC or not. This is detailed in Section R.17.3.

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

Tier 1 screening equations are available for environmental exposure, inhalation exposure, skin exposure and systemic exposure from multiple pathways. The exposure estimation should accurately reflect article handling, conditions of use and related exposure characteristics (contact time, frequency of contact, exposure pathways etc.).

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

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

When using calculations based on Article Categories (see Appendix R.12-4 and Appendix D-3.3), the assumptions of any defaults in a category must be checked against the exposure pathways and environmental release patterns for that particular article category, and adapted if needed.

Step 2: Refinement of the Tier 1 exposure estimation

The Tier 1 assessment can be improved by refining the assumptions. This can be done, e.g. by using more elaborate models to estimate the release or uptake rate of substances, as discussed in Section R.17.4, or by using measured data.

Measured data on leaching, release or exposure concentrations can be used as input parameters for the assessment models. The release data for the relevant exposure pathway can be compared to the DNEL for short- or long term exposure or to the PNECs for environmental compartments.

- For human exposure, the release of substances from the article matrix into the relevant contact media such as air, (drinking) water, fluid (saliva or gastro-intestinal fluids) or skin (dermal exposure) can be measured with standardized test methods (e.g. using the test methods of Appendix R.17-1). It should be established whether substances migrate from the matrix in the mouth or (also) in the gastro-intestinal tract.
- The environmental exposure estimation should focus on release to air, water or soil/sediment by evaporation, leaching into (pore) water or particle abrasion. The release of substances into environmental media can be refined, e.g. by measured leaching rates etc.

Step 3: Higher tier exposure estimation

If the previous steps still cannot demonstrate control of risks, higher tier assessment can be considered. Higher tier specific exposure models can be used or additional release or exposure information can be collected or measured. In particular, measured data or models for release from a matrix can be used to further refine the assessment. Several tools and information sources are available for this (see Appendix R.17-1: Collecting information on release rates from articles). Higher tier models for consumer exposure estimation are discussed in Section R.15.5.

R.17.3 Release and exposure estimation for humans

The safety of an article for screening purposes can be demonstrated from the composition of the article. The reasonable worst case assumption is that all of the substance contained in the article is released instantaneously and is available for inhalation, dermal or oral uptake. If the article is a composite, the relevant part of the article is used for article weight. Measured data of good quality should be used whenever available. The sections below briefly state the assumptions and refer back to Chapter R.15 on consumer exposure estimation.

R.17.3.1 Inhalation

R.17.3.1.1 Volatile substances

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

- Use the Tier 1 inhalation model (Section R.15.4).

R.17.3.1.2 Inhalation of particles or dust

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

- Use the Tier 1 inhalation model (Section R.15.4, with a conservative assumption on the inhalable and/or respirable fraction. The non-respirable fraction can be swallowed and oral exposure may also need to be considered.

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

R.17.3.2 Dermal contact

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

- Use the Tier 1 dermal exposure model B: a non-volatile substance migrating from an article (Section R.15.4).

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

R.17.3.3 Ingestion

R.17.3.3.1 Ingestion of a product or an article

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

- Use the Tier 1 oral exposure model A: Unintentional swallowing during normal use (Section R.15.4). If the article is diluted before use, an additional dilution term can be added to the equation above.

R.17.3.3.2 Migration from an article

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

- For a screening assumption on migration, use also the Tier 1 oral exposure model A: Unintentional swallowing during normal use (Section R.15.4).

- For mouthing behaviour of children, use parameters provided in Van Engelen et al., 2006 (Appendix R.17-1).

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

R.17.3.4 Eye contact

It is assumed that eye contact is usually not a relevant exposure pathway for articles, with a few exceptions, e.g. contact lenses. In those cases, consider using the dermal models (see previous Section R.17.3.2).

R.17.4 Release and exposure estimation for the environment

R.17.4.1 General considerations

For environmental exposure to substances in articles, the aggregate emissions from the total weight or area of the articles in which the substance is contained should be taken into account instead of the weight or shape of a single object handled, chewed on or ingested as when human exposure is assessed.

If it is assumed that release of all of the substance occurs during service life, release due to product use should not be added to the total to avoid double counting of the substance. It is assumed that the releases of substances during manufacture of the article are covered by a regular CSA if the substance is manufactured in the EU.

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

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

A usual Tier 1 screening taking the service life of the article into account is to assume a constant release rate over time, called ‘emission factor’ [%] ($\text{Fservice life}_{\text{comp}}$) if the surface area is not the controlling factor for release:

$$\text{Rtot}_{\text{comp}} = \text{Fservice life}_{\text{comp}} \cdot \text{Atot} \cdot \text{Fc}_{\text{article}} \cdot T_{SL\_article} \qquad \textbf{Equation 17-1}$$

Parameter	Description	Unit	Source
$Rtot_{comp}$	Annual total release of the substance to a certain environmental compartment (comp) over the service life of the products at steady state	[kg/yr]	
F service life $_{comp}$	Emission factor to a certain environmental compartment over service life of the articles [%] (estimated or measured)	[-]	
Atot	Yearly total input of the articles	[kg/yr]	
$Fc_{article}$	Weight fraction of substance in article	[-]	
$T_{SL\_article}$	Service life of articles	[yr]	

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

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

$$\text{Rtot\_Subst}_{\text{comp}} = F_{area,camp} \times Area_{article} \times T_{sl\_article}$$ **Equation 17-2**

Parameter	Description	Unit	Source
$Rtot\_Subst_{comp}$	Annual total release of the substance to a certain environmental compartment (comp) over the service life of the products at steady state	[$kg.yr^{-1}$]	
$F_{area,\ comp}$	Annual emission factor to an environmental compartment (comp) on an article- area basis	[$kg.m^{-2}.year^{-1}$]	
$Area_{article}$	Annual emitting surface area	[$m^2.yr^{-1}$]	
$T_{sl\_article}$	Service life of articles	[yr]	

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

More detailed calculations of emissions from articles can be performed by using the equations in the next sections. This process is simplified by using the ERCs as described in Part D4.4 and Appendix D-3 and Section R.16.2 for the relevant process and article category that is applicable to the articles.

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

1. Estimate the service life of the article.
2. Consider the emission type (molecular and/or particulate).
3. Estimate emission factors for the substance from the actual material (e.g. fraction/tonne or $mg.m^{-2}$ surface area). If emission data are missing:
    - Compare with similar articles described in ESD’s or other sources;

  - Search for data in the literature;
  - Use a worst-case assumption or if necessary perform an emission study, leaching study etc.
4. Calculate the total releases of substance from articles at steady state.
5. Calculate the regional releases representing a densely populated area.

R.17.4.2 Detailed release estimation for service life

R.17.4.2.1 Considerations

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

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

R.17.4.2.2 Input data

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

1. Article types in which his substance is used and

2. The average service life of these products.

3. The fraction of the marketed volume used in certain product types.

4. An emission factor (release rate) per year. In a Tier 1 assessment, a default emission factor can be used based on the ERCs (see Section R.16.2). Specific information can be used to substitute the defaults, e.g. based on models (for example for packaging materials) or based on testing.

R.17.4.2.3 Estimate the service life of the article

A list of examples for service life spans and release factors taken from the emission scenario document on plastic additives is presented in Table R.17-1. For an overview of available emission scenario documents, see Annex R.16-2.

Table R.17-1 Example of service life and release factors (per year) for polymer articles

Article type	Typical service life time	Release factor for a plasticizer, medium volatility	Release factor for a flame retardant or a 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		

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

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

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

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

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

R.17.4.2.5 Emission Factors

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

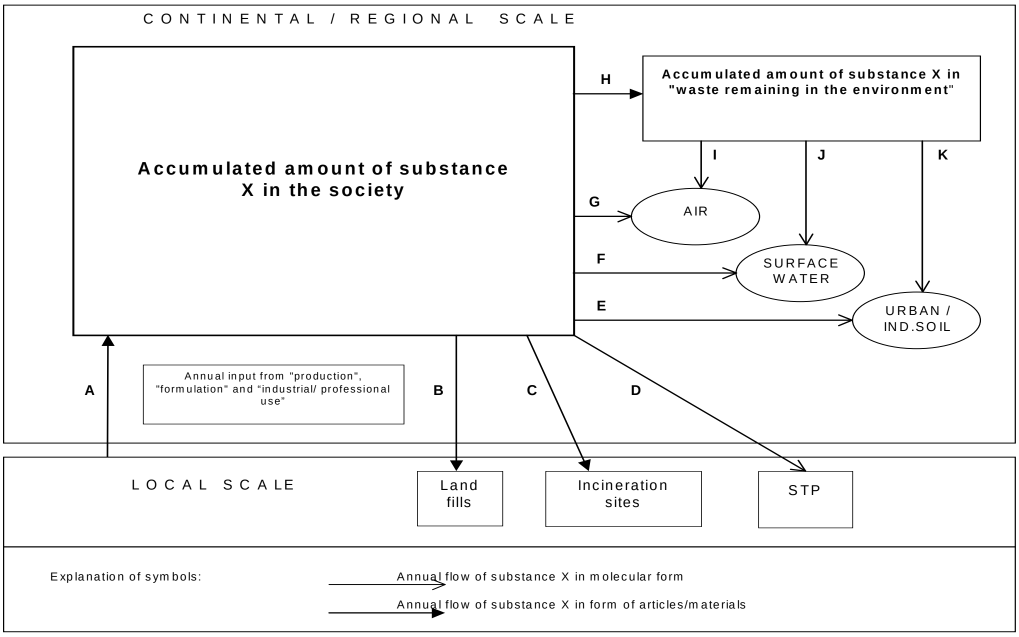
The emission factors are driven by the following main characteristics of the substance, the article and the environment:

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

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

R.17.4.2.6 Calculate the total releases of substance

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



(A = B + C + D + E + F + G + H for society;
H = I + J + K for "waste remaining in the environment").

Figure R.17-1 Emissions from long-life articles at steady state

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

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

$$RELEASEtot\_steadystate_{i,j,k} = F_{i,j} \cdot Qtot\_accum\_steadystate_k$$ **Equation 17-3**

and:

$$RELEASEtot\_steadystate_{i,total,k} = F_{i,total} \cdot Qtot\_accum\_steadystate_k$$ **Equation 17-4**

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

$$Qtot\_accum\_steadystate_k = Qtot_k \cdot \sum_{y=1}^{Tservice_k} (1 - F_{i,total})^{y-1}$$ **Equation 17-5**

In situations where the emission factor is low (< 1%.yr^{-1}) and the service life of the product is not very long, the emissions and accumulation at steady state (Equations 17-7 to 17-9) can be simplified as:

$$RELEASEtot\_steadystate_{i,j,k} = F_{i,j} \cdot Qtot_k \cdot Tservice_k$$ **Equation 17-6**

$$RELEASEtot\_steadystate_{i,total,k} = F_{i,total} \cdot Qtot_k \cdot Tservice_k$$ **Equation 17-7**

$$Qtot\_accum\_steadystate_k = Qtot_k \cdot Tservice_k$$ **Equation 17-8**

Explanation of symbols

Parameter	Description	Unit	Source
$F_{i,j}$	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)]
RELEASEtot_steady state$_{i,j,k}$	Annual total release during life cycle state i to compartment j at steady state for product k	[tonnes · yr^{-1}]	
RELEASEtot_steady state$_{i,total,k}$	Annual total releases during life cycle state i to all relevant compartments at steady state for product k	[tonnes · yr^{-1}]	
Qtot$_k$	Annual input of the substance in product k	[tonnes · yr^{-1}]	data set
Qtot_accum_steady state$_k$	Total quantity of the substance accumulated in product k at steady state	[tonnes]	
Tservice$_k$	Service life of product k	[yr]	data set

[1)] Alternatively use Equation 17-12

[2)] Alternatively use Equation 17-13

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

$$QWASTEtot\_steadystate_k = Qtot_k - RELEASEtot\_steadystate_{i,total,k}$$ **Equation 17-9**

Explanation of symbols

Parameter	Description	Unit	Source
QWASTEtot_steady state$_k$	Total quantity of the substance in product k ending up as waste at steady state	[tonnes · yr^{-1}]	
Qtot$_k$	Annual input of the substance in product *k*	[tonnes · yr^{-1}]	data set
RELEASEtot_steady state$_{i,total,k}$	Annual total releases during life cycle stage i to all relevant compartments at steady state for product *k*	[tonnes · yr^{-1}]	Equation 17-4 Equation 17-7

R.17.4.2.7 Calculate the regional releases

Using a 10% default (which can be substituted with any other percentage if indicated by e.g. market survey data) the annual regional release from article k to compartment j and for the total of all compartments can be calculated as:

$$RELEASEreg\_steadystate_{i,j,k} = RELEASEtot\_steadystate_{i,j,k} \cdot 0.1$$ **Equation 17-10**

and:

$$RELEASEreg\_steadystate_{i,total,k} = RELEASEtot\_steadystate_{i,total,k} \cdot 0.1$$ **Equation 17-11**

Explanation of symbols

Parameter	**Description**	**Unit**	**Source**
RELEASEreg_steady state$_{i,j,k}$	Annual regional release during life cycle i to compartment *j* at steady state for product *k*	[tonnes · yr^{-1}]	
RELEASEreg_steady state$_{i,total,k}$	Annual regional release during life cycle i to all relevant compartments at steady state for product *k*	[tonnes · yr^{-1}]	
RELEASEtot_steady state$_{i,j,k}$	Annual total release during life cycle i to compartment *j* at steady state for product *k*	[tonnes · yr^{-1}]	Equation 17-6
RELEASEtot_steady state$_{i,total,k}$	Annual total release during life cycle i to all relevant compartments at steady state for product *k*	[tonnes · yr^{-1}]	Equation 17-4 Equation 17-7

These regional diffuse releases are then added to the regional emissions calculated from non-diffuse emissions (Eregional$_j$).

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

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

and:

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

Explanation of symbols

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

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

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

Releases from articles will normally only contribute to the regional releases. The emissions from indoor uses can be released to wastewater and therefore be regarded as a point source (stream *D* in Figure R.17-1). Also outdoor uses may cause releases to STP if the storm water system is connected to the STP. This has to be considered case by case.

R.17.5 Refined exposure estimation

R.17.5.1 Release rates of substances from articles

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

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

Two main possibilities are distinguished:

- The release is controlled by the user of the article (e.g., release of ink from a pen) and therefore dependent on use frequency and use time per event. The release is constant over the time of use to ensure its function.

- The release is controlled by the matrix of the article, e.g. scented objects. The release is declining over time because the total amount of substance in the object declines over time (usually approximated by first-order release kinetics).

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

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

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

R.17.6 Control of risks

Exposure from a pathway or a combination of pathways should not exceed the DNEL (for humans) or the PNEC (for environment). Refinement of the exposure estimation will have to be carried out until the exposure estimates are below the DNEL or the PNEC (see Section R.17.1.5). For further information on risk characterization, see Part E.

R.17.7 References

Fischer, S (2006). Complementing Guideline for writing ESD's: The life-cycle step "Service-life". Draft document for the OECD Task Force on Environmental Exposure Assessment, June 2006.

OECD (2004). Emission scenario document on plastics additives. Series on Emission Scenario Documents No. 3. Environmental Health and Safety Publications, ENV/JM/MONO(2004)8 OECD.

Oomen AG, Rompelberg CJM, Bruil MA, Dobbe CJG, Pereboom DPKH, Sips AJAM. (2003). Development of an in vitro digestion model for estimating the bioaccessibility of soil contaminants. Arch. Environ. Contam. Toxicol. 44: 281–287.

Petersen J.H., Trier X.T., Fabech B (2005). Mathematical modelling of migration: A suitable tool for the enforcement authorities? Food Additives and Contaminants 22: 938–944.

Van Engelen et al. (2006). Chemicals in toys. A general methodology for assessment of chemical safety of toys with a focus on elements. RIVM/SIR advisory report 0010278A02.

APPENDIX R.17-1: COLLECTING INFORMATION ON RELEASE RATES FROM ARTICLES

Available data

Annex 7 of the Guidance on requirements for substances in articles lists many sources of substances in articles. These sources should be consulted for a specific type or class of articles. Another source for exposure estimation for articles is the EIS-Chemrisk database (http://web.jrc.ec.europa.eu/eis-chemrisks/toolbox). A registration is required in order to use the database.

Model estimations

Specific migration estimation models exist, for instance for release of substances from plastic or polymer products (http://www.specialchem4polymers.com/).. Migration models can be helpful in the context of risk assessment (Petersen et al., 2005).

Testing methods

Human exposure

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

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