Exposure assessment principles and EUSES under REACH

Workshop on EUSES update needs
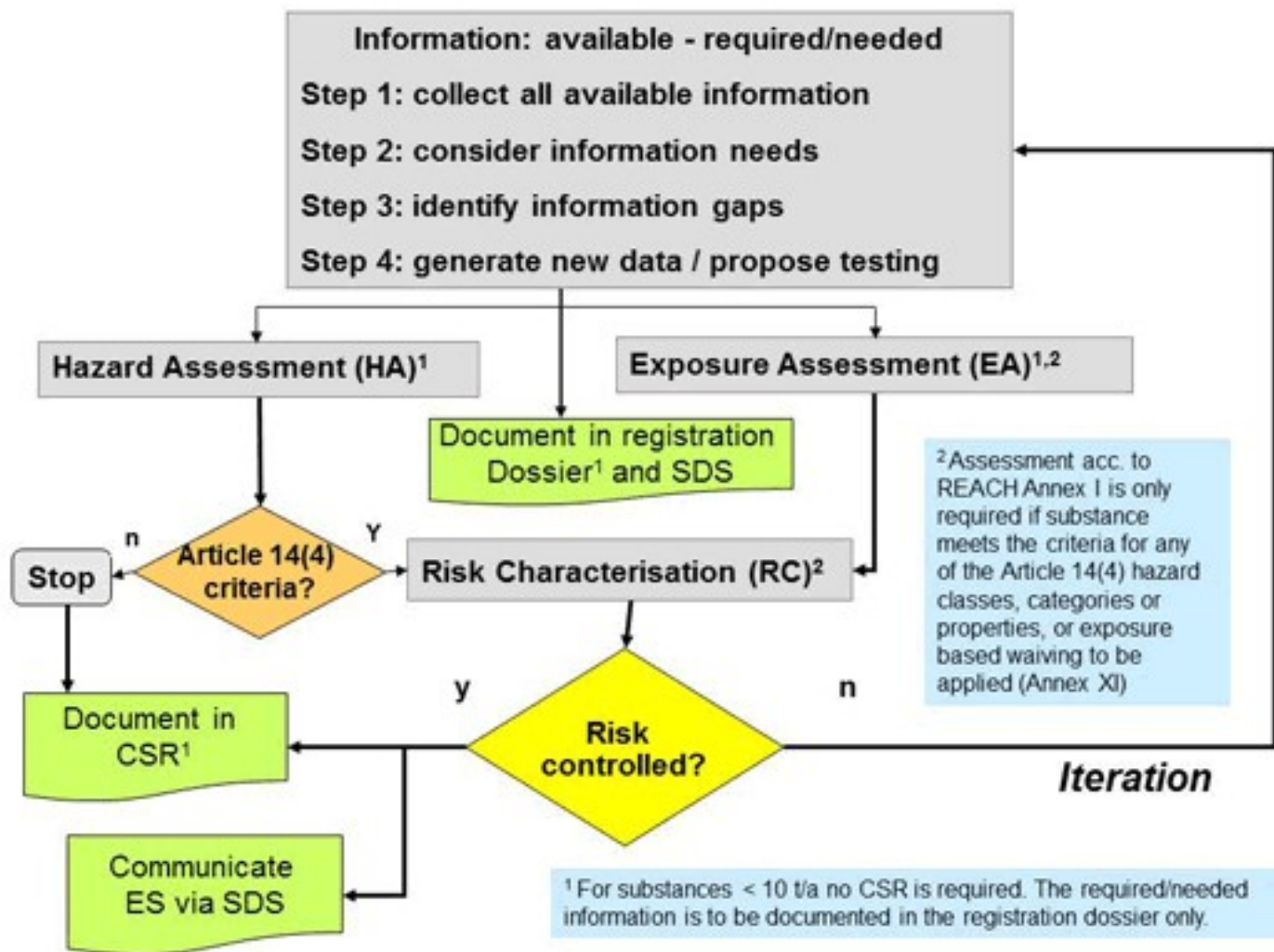
4-5 June 2018

Romanas Cesnaitis
ECHA, Evaluation E1

Outline

- Legal requirements
- Use mapping and use description
- Release (emission) assessment
- Release scenarios and predicted environmental concentrations

Information requirements and chemical safety assessment under REACH

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Information: available - required/needed

Step 1: collect all available information

Step 2: consider information needs

Step 3: identify information gaps

Step 4: generate new data / propose testing

Hazard Assessment (HA)[1]

Exposure Assessment (EA)[1,2]

Document in registration Dossier[1] and SDS

[2] Assessment acc. to REACH Annex I is only required if substance meets the criteria for any of the Article 14(4) hazard classes, categories or properties, or exposure based waiving to be applied (Annex XI)

Stop

Article 14(4) criteria? n Y

Risk Characterisation (RC)[2]

Document in CSR[1]

Risk controlled? y n

Communicate ES via SDS

Iteration

[1] For substances < 10 t/a no CSR is required. The required/needed information is to be documented in the registration dossier only.

MH1   This is not key for this presentation but yu selected a relatively heavy version ofthis. In particular teh middle bloc with teh 4 steps and the document in registration is quite duplicating the other boxes in my view

MAGAUD Helene, 24/05/2018

Legal requirements

Annex I, section 5. Exposure assessment

- Quantitative or qualitative estimate of the dose/concentrations to which environment may be exposed

- All life-cycle stages from manufacture and identified uses shall be considered and shall cover any exposures that may relate to the **hazards** identified

- Step 0: Mapping of uses

- Step 1: Generation of Exposure Scenarios (Annex I 5.1.1)
  - Operational conditions
  - RMMs (including waste management measures where relevant)

- Step 2: Exposure Estimation (Annex I 5.2.1)
  - emission estimation
  - assessment of chemical fate and pathways
  - estimation of exposure levels (a number of factors to be considered)

- If risk characterisation indicates that risk is not controlled, the exposure assessment may need to be refined

Env. protection targets:
1) *Aquatic (including sediment) compartment;*
2) *Terrestrial compartment;*
3) *Atmospheric compartment;*
4) *Accumulation via food-chain; and*
5) *Microbiological activity of sewage treatment systems.*
6) *Man via environment*

- Relevant ECHA's Guidance on IR&CSA:
  - Part D: Framework for exposure assessment
  - Chapter R.12, Use description
  - Chapter R.13, Risk management measures and operational conditions
  - Chapter R.16, Environmental exposure assessment $\rightarrow$ the approach and methodology used in EUSES (system based on EU-TGD, 2003) is followed
  - Chapter R.18, Estimation of exposure from waste

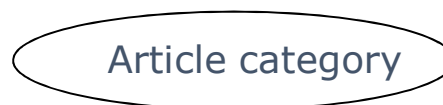![ECHA - European Chemicals Agency] **Use mapping**

Identification and description of uses is key for the safety assessment (where all relevant life-cycle stages should be considered)!

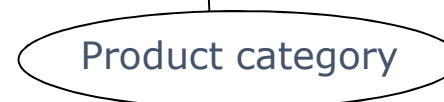- Use name and further description of use

- Life cycle stage

Article category

Sector of use

- Identification of the markets in which the substance is used

Environmental release category

Product category

- Description of the different activities contributing to the uses (from human health and environment perspectives)
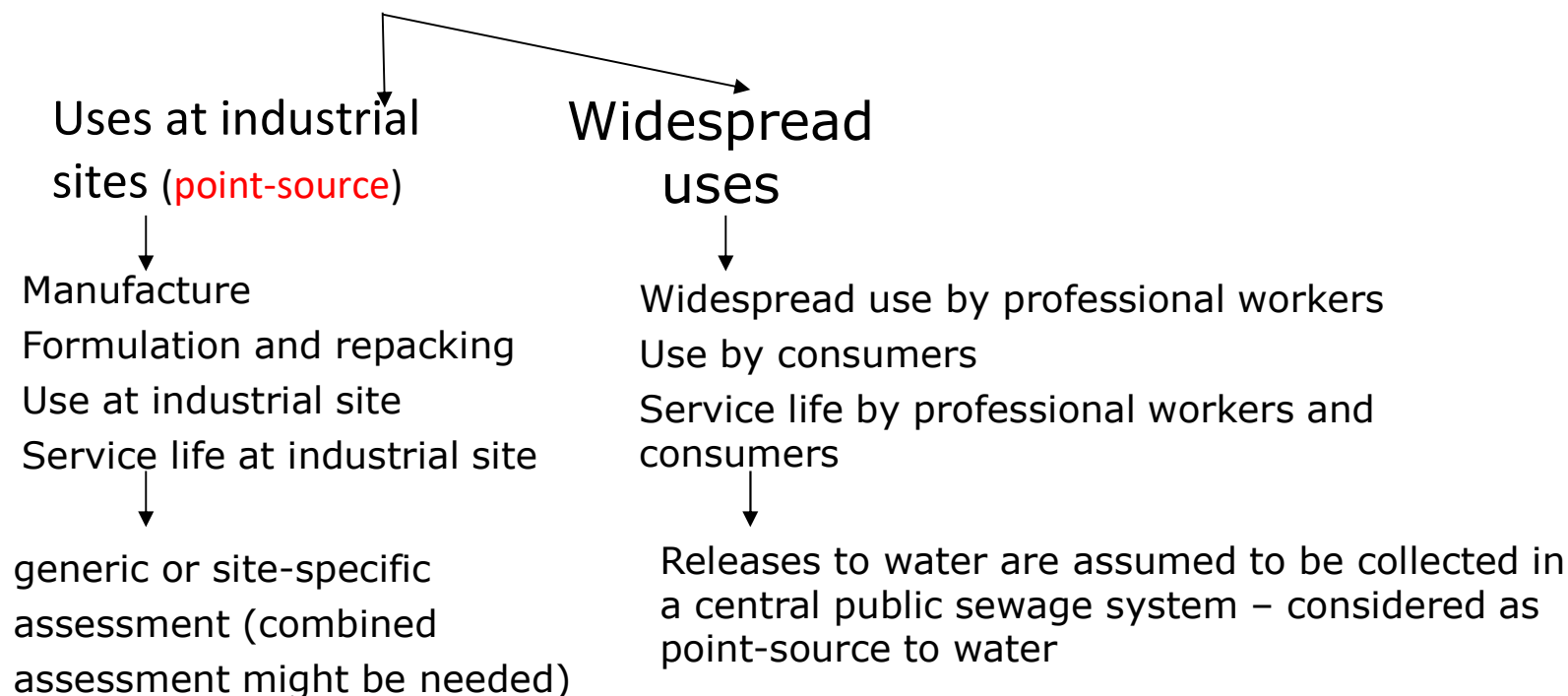
Process category

- Technical function of the substance in the use

- Use maps - generated by downstream user sector organisations present uses and the conditions of use of chemicals in their sector in a harmonised and structured way
- Use maps library on *https://echa.europa.eu/csr-es-roadmap/use-maps/use-maps-library*

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Exposure assessment

- Release (with subsequent exposure) are assessed at two spatial scales

- Local and regional environments are standardised environments based on generic parameters

Local scale
in the vicinity of release source

Regional scale
includes all release sources in that area

Uses at industrial sites (point-source)

Widespread uses

Manufacture
Formulation and repacking
Use at industrial site
Service life at industrial site

Widespread use by professional workers
Use by consumers
Service life by professional workers and consumers

generic or site-specific assessment (combined assessment might be needed)

Releases to water are assumed to be collected in a central public sewage system – considered as point-source to water

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Release (emission) assessment (estimation)

- Aim is to calculate the **release rates -** the main input parameters to be fed into the exposure estimation
- Release rate = release factor x tonnage

Release factor –expresses the fraction (either kg/kg or %) of the used amount being released to a given release route

used in a standard town for widespread uses

used at a typical industrial site

used at regional scale for each use

Estimation of the release rates
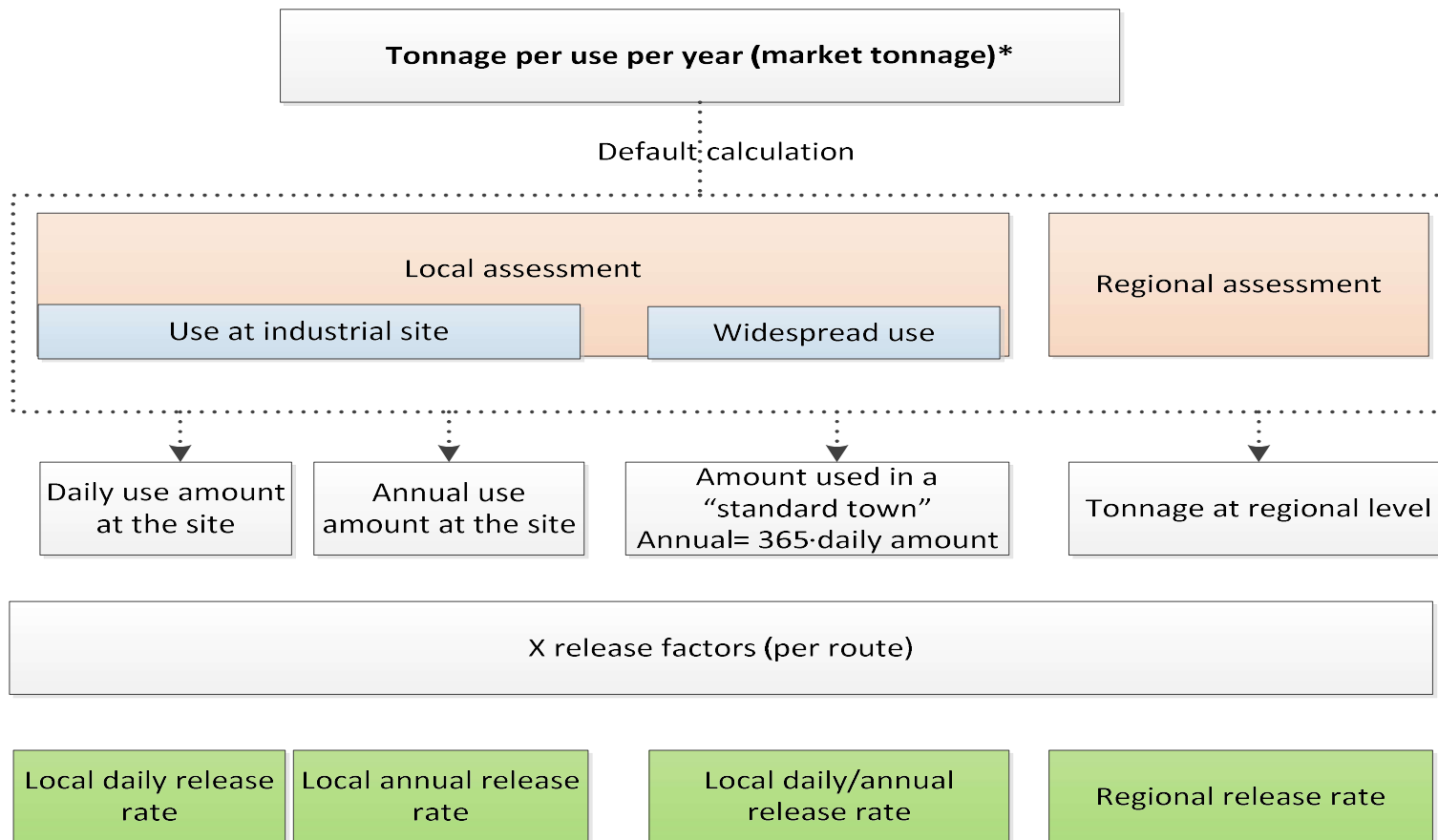
Release factors

Ideally, should be based on actual measurements of releases to various compartments

Default release factors are defined for different Environmental Release Categories (ERC) (ECHA guidance R.16.). They depend on the use of the substance and are defined for different compartments: air, wastewater, soil.
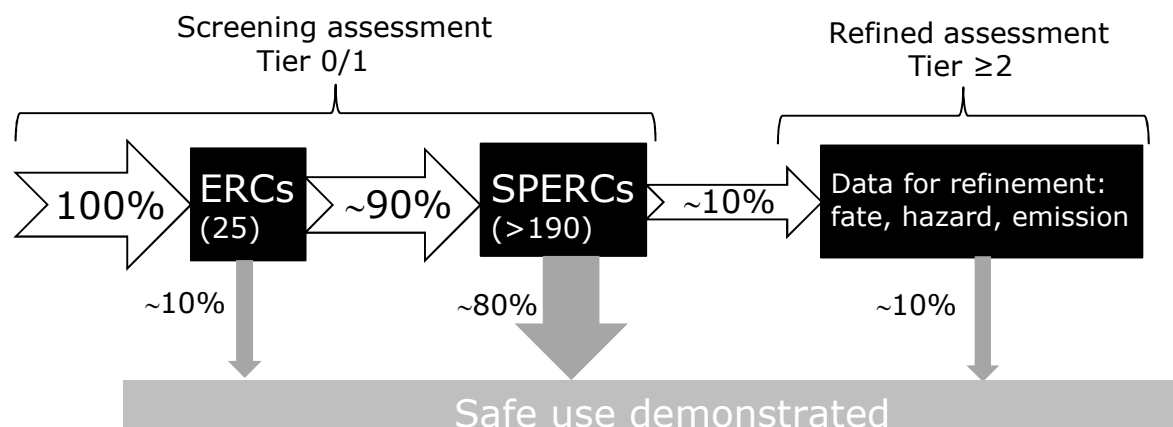
Environmental Release Categories (ERCs):

- No on-site RMMs assumed
- Set of default conservative release factors (RFs)
- Sum of RFs for some ERCs is above 100% (e.g. RFs of 100% each to water, air and soil for ERC 10b Widespread use of articles with high or intended release (outdoor))

When more specific information (on operational conditions (OCs), risk management measures (RMMs) etc.) is available refined release factors can be used: e.g. sector specific ERCs (SPERCs), site-specific information, OECD emission scenario documents, Best Available Techniques (BAT).

A and B tables of the TGD (2003) are not acceptable, unless they clearly provide more specific information on RMMs/OCs and link them to the release factors proposed

SPERCs
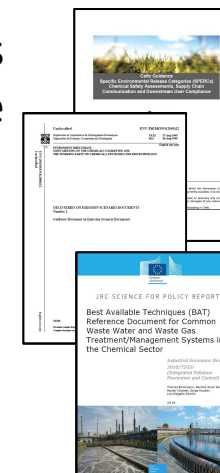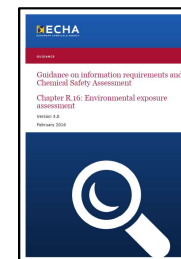
- Industry analysis of ERCs (2008)
  - Identifies safe use in rare cases
  - Useful for the grouping of uses and technical functions
- Conclusion: adopt ERCs as framework for release assessment and develop Specific Environmental Release Categories (SPERCs) based on ERCs
  - Developed by industry
  - Refined release assessment (vs ERCs)
  - For use by registrant in their CSAs
  - Element of lower tier environmental exposure assessment

Screening assessment Tier 0/1

Refined assessment Tier ≥2

100% | ERCs (25) | ~90% | SPERCs (>190) | ~10% | Data for refinement: fate, hazard, emission

~10% | ~80% | ~10%

Safe use demonstrated

Antonia Reihlen, Ökopol. SPERCs – An Introduction, SPERC Workshop on 13 May 2016, Brussels

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SPERCs

- Reihlen A, Bakker J, 2014. Assessment of reliability of SPERCs. Final Report. Helsinki, Finland: European Chemicals Agency. Contract No ECHA/2011/01; Service request SR 16.

- Important to provide clear and targeted documentation – via two types of documents
  - Factsheet
    - OCs/RMMs
    - Release assessment inputs
  - Background document
    - Details on processes, assumptions
    - Justification of release factors
    - Substance use rates or info enabling estimation of these rates

SPERC development

ENES (Expert Network on Exposure Scenario) action 2.3, lead by SPERC industry task force

Objective:

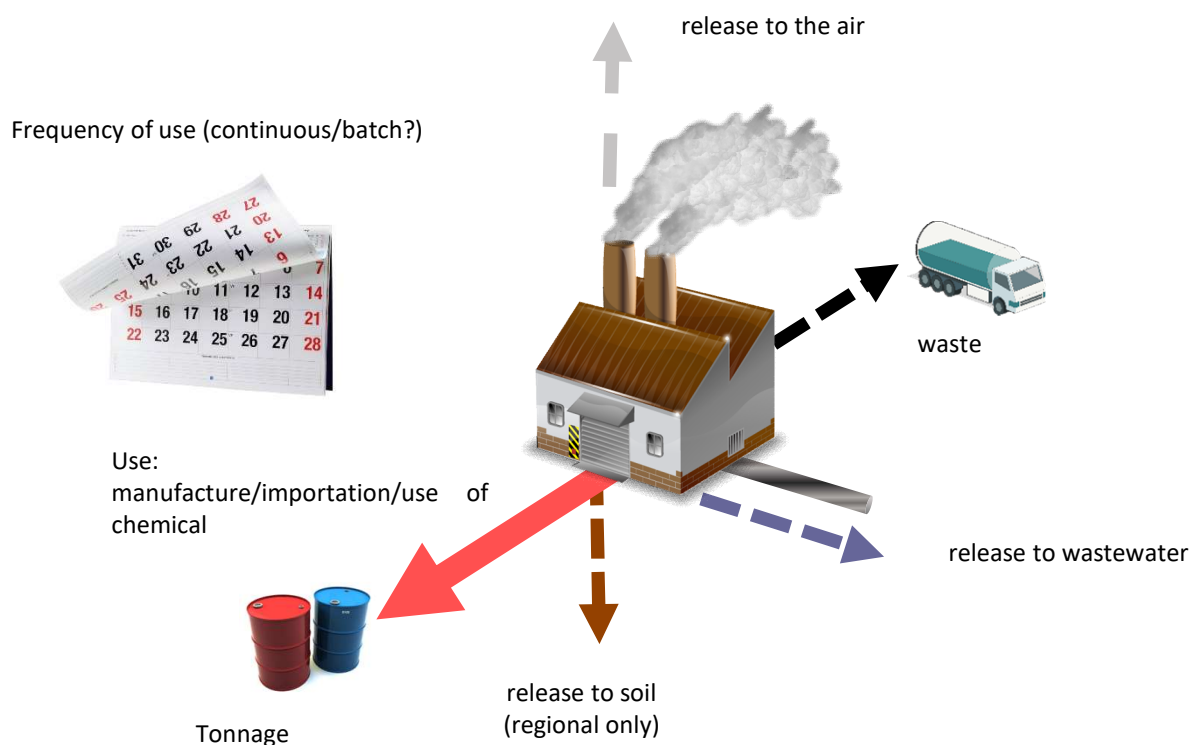Increase quality of existing SPERCs and increase availability of SPERCs

2018 work plan:

- Development of SPERC quality criteria (Q2 2018)
- Development of background documents and review of existing SPERCs by industry (Q3-Q4 2018)

- ECHA/Member States invited to provide their comments on the quality criteria developed by the TF

Local release estimation: tonnage at industrial settings

Unless site specific data are available, the annual tonnage at a site should be **100% of the total annual tonnage for the use**

$$\text{Release rate}_{comp,use} \text{ [tonnes/day]} = \frac{\text{Annual tonnage at the site [tonnes/year]}}{\text{Number of release days [days/year]}} \times \text{Release factor}_{comp,use} \text{ [% or kg/kg]}$$

release to the air

Frequency of use (continuous/batch?)

Use: manufacture/importation/use of chemical

Tonnage

waste

release to wastewater

release to soil (regional only)

Large tonnages are more likely to be manufactured or used continuously. E.g. for manufacture:

Tonnage of the substance manufactured per year	No. of release days (days/year)
Tonnage < 1 000	20
1000 < Tonnage < 10 000	100
Tonnage> 10 000	300

(See R.16.2.2.1.1.)

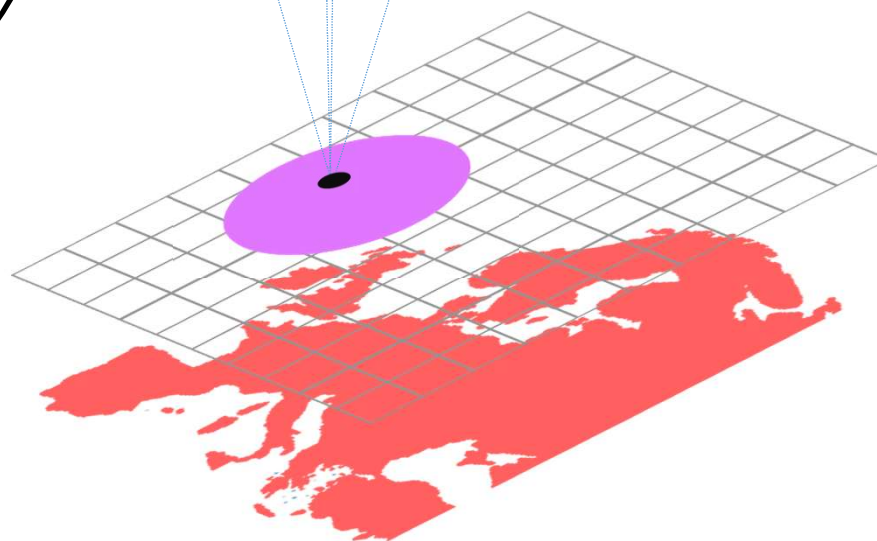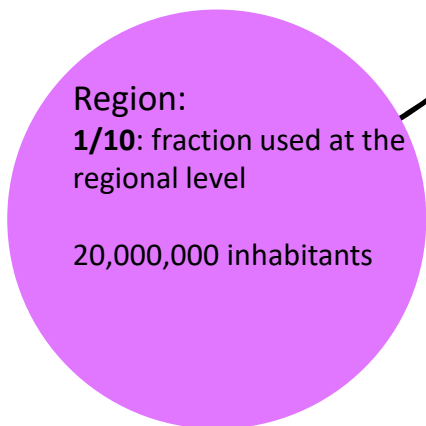# Local release estimation:
tonnage for wide dispersive use

Total registered tonnage [tonnes/year]

Other uses

Annual tonnage for the use [tonnes/year]

Used **365 days/year**

Standard town:
1/2000: fraction used in a standard town of 10,000 inhabitants

Safety factor: **4**
Geographical or temporal peaks

Region:
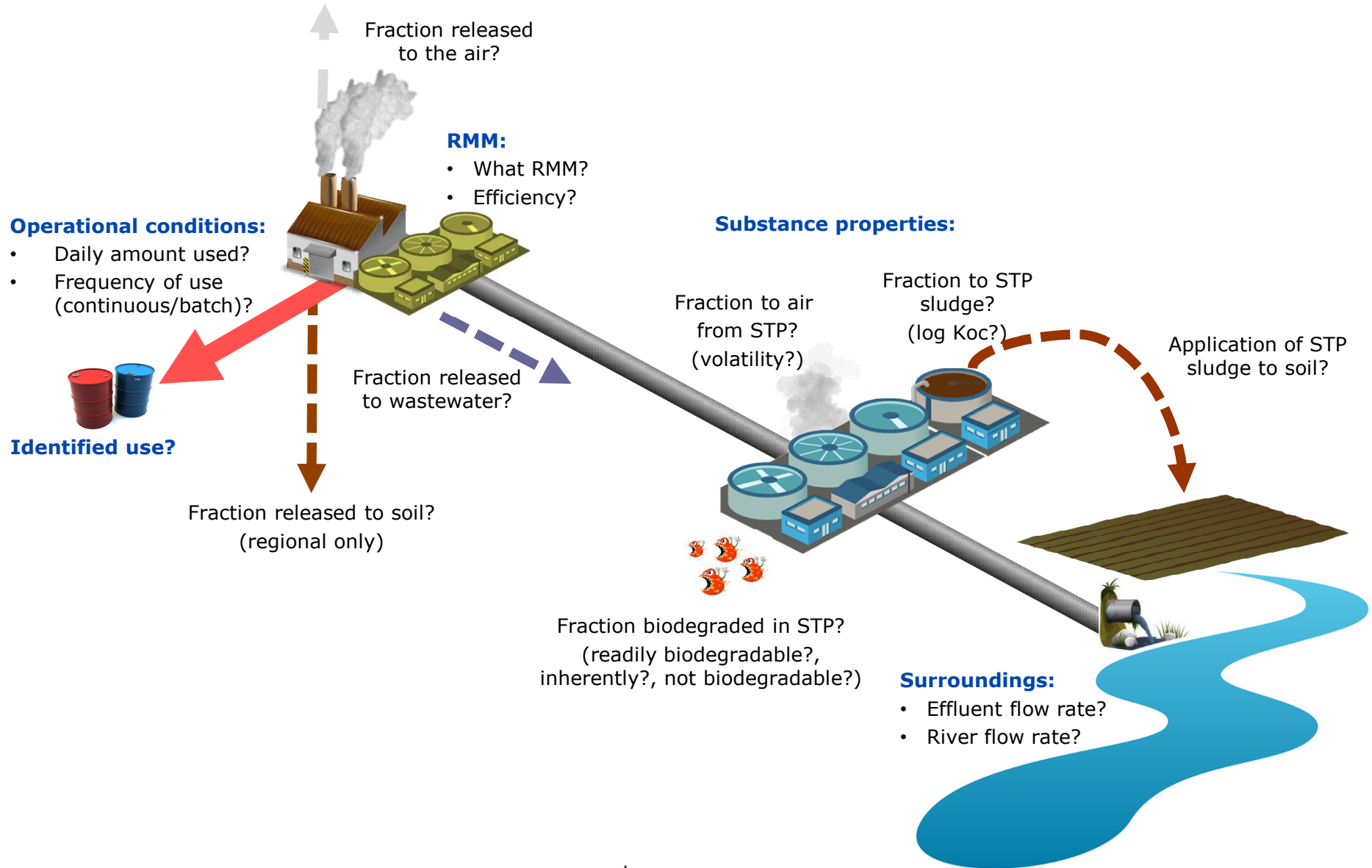**1/10**: fraction used at the regional level
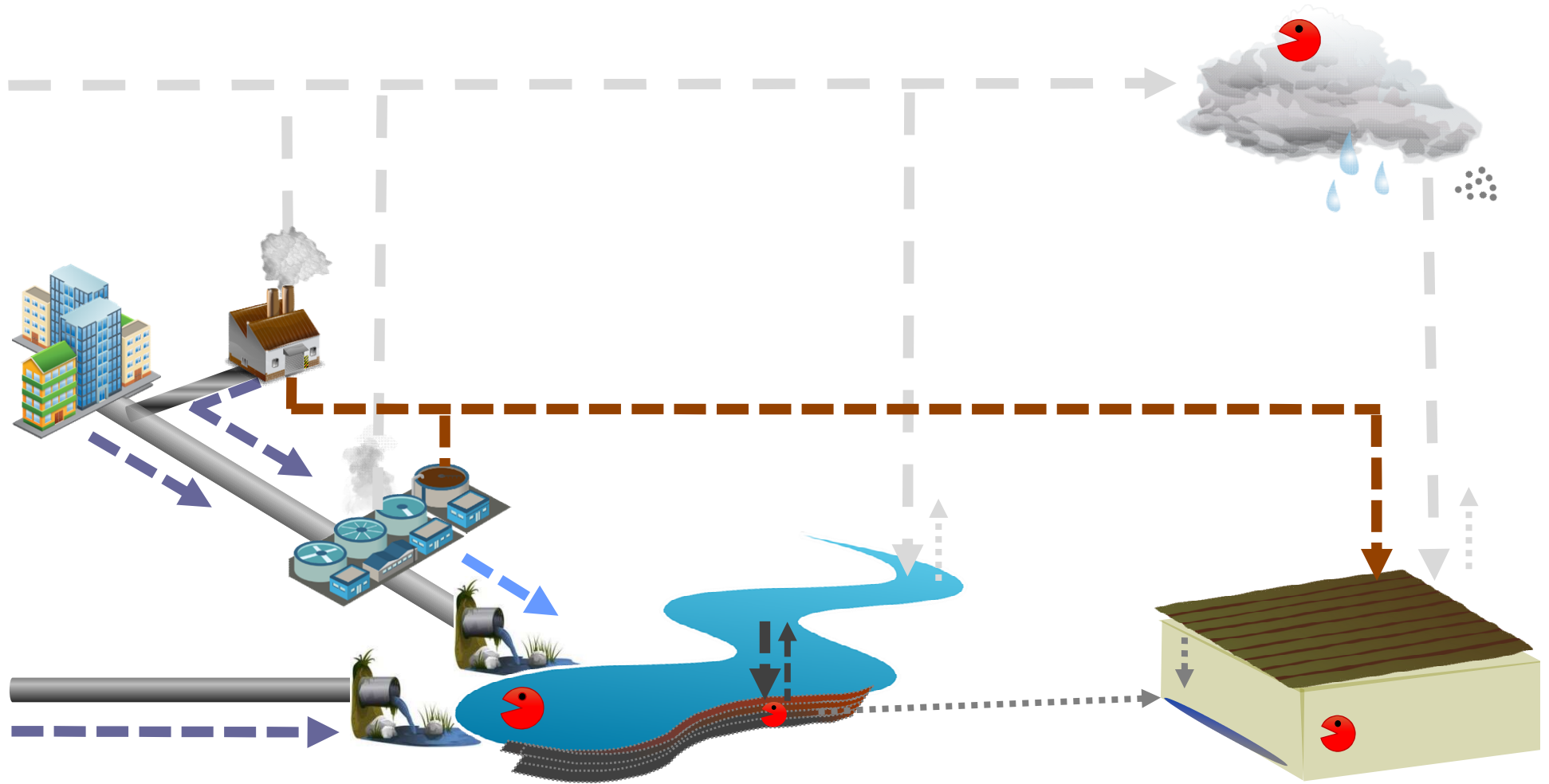
20,000,000 inhabitants

Daily use in a standard town [tonnes/day] = $\dfrac{\text{Annual tonnage for the use [tonnes/year]} \times 4}{10 \times 2000 \times 365 \text{ [days/year]}}$

Release rate$_{comp,use}$ [tonnes/day] = Daily use in a standard town [tonnes/day] × Release factor$_{comp,use}$

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Release scenario

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Fraction released to the air?

RMM:
- What RMM?
- Efficiency?

Operational conditions:
- Daily amount used?
- Frequency of use (continuous/batch)?

Identified use?

Fraction released to wastewater?

Fraction released to soil? (regional only)

Substance properties:

Fraction to air from STP? (volatility?)

Fraction to STP sludge? (log Koc?)

Application of STP sludge to soil?

Fraction biodegraded in STP? (readily biodegradable?, inherently?, not biodegradable?)

Surroundings:
- Effluent flow rate?
- River flow rate?

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Distribution in the environment

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Environmental protection targets

Protection target		Related compartment	PNEC
Biological sewage treatment plant:	Microorganisms	Sewage treatment plant aeration tank	$PNEC_{micro-organisms}$
Freshwater ecosystem:	Freshwater organisms	Freshwater	$PNEC_{water}$ (freshwater)
	Sediment organisms	Freshwater sediments	$PNEC_{sed}$ (freshwater)
	(Fish eating) predators[1]	Fish	$PNEC_{oral}$
Marine ecosystem:	Marine water organisms	Marine water	$PNEC_{saltwater}$
	Sediment organisms	Marine sediments	$PNEC_{sed,marine}$
	(Fish eating) predators[5]	Marine fish	$PNEC_{oral}$
	Top predators[5]	Marine predators	$PNEC_{oral}$
Terrestrial ecosystem:	Agricultural soil organisms	Agricultural soil	$PNEC_{soil}$
	(Worm eating) predators[5]	Earthworms	$PNEC_{oral}$
Air	Atmosphere	Air	$PNEC_{air}$2

Plus humans exposed via the environment to be protected: exposure via inhalation and oral route are assessed and compared to hazard estimates

http://echa.europa.eu

Some limitations of the modelling approach in R.16./EUSES

Offshore uses

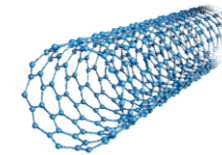Agricultural spraying (e.g. co-formulants in PPP)

Emissions from road/railways (brakes and tyres wear, de-icing, asphalt, etc.)

Fracking (emission to groundwater)

Metals

Nanomaterials

Surface active substances

Ionisable organic substances

More other scenarios and substances!

Thank You. Questions?

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