

# Exposure assessment principles and EUSES under BPR

**EUSES Update workshop**  
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## Outline

- What are biocides?
- Where to find guidance on exposure assessment?
- Principles of exposure assessment
- Biocides in EUSES

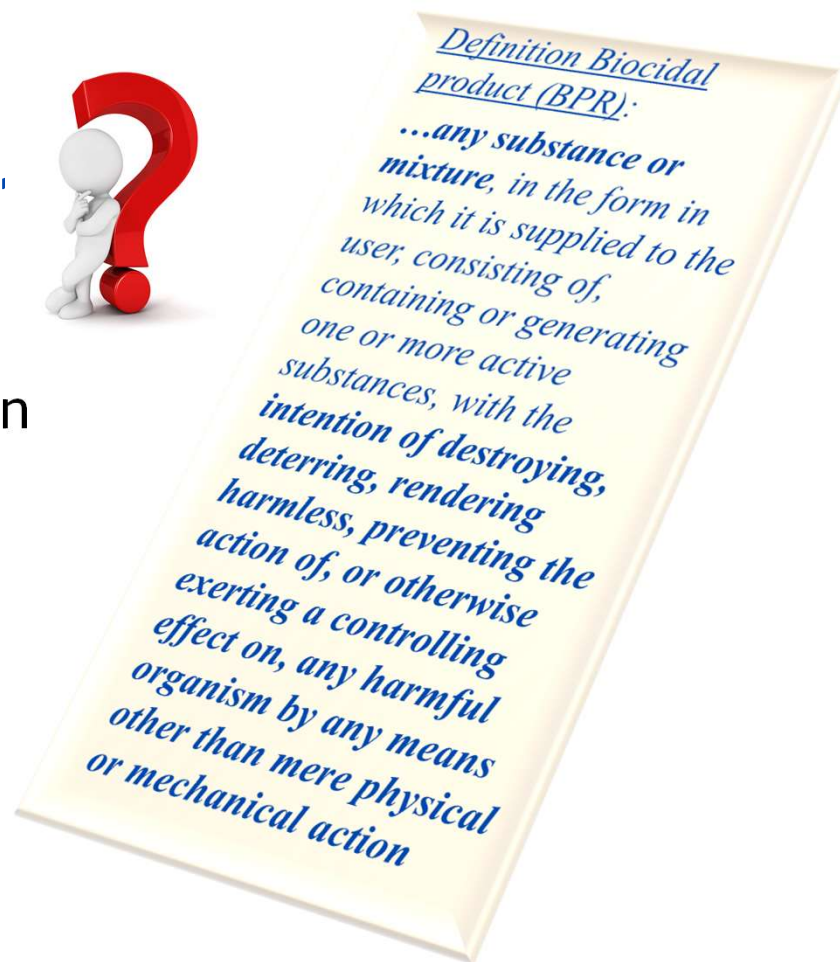


## What are biocides (for)

### Control of organisms

- that would be harmful to human or animal health
- cause damage to natural or manufactured products  
...when not covered by another legislation: pharmaceutical, plant protection, veterinary, cosmetic product

- Legal text: Regulation (EU) No 528/2012 ... concerning the making available on the market and use of biocidal products (BPR)
- Concept of biocidal product containing biocidal active substanc(es) which are (EU) approved per product type (PT)



## Main groups and product types (PT)

### Disinfectants

- ⇒ Human hygiene (1), public health (2), veterinary (3), food and feed areas (4), drinking water (5)

### Preservatives

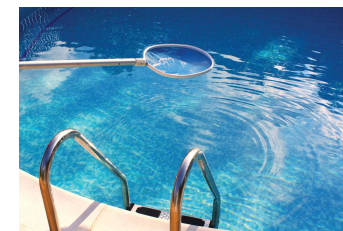
- ⇒ In-can (6), film (7), wood (8), fibre (9), construction material (10), liquid cooling (11), slimicides (12), working fluids (13)

### Pest control

- ⇒ rodenticides (14), insecticides (18), repellents (19)

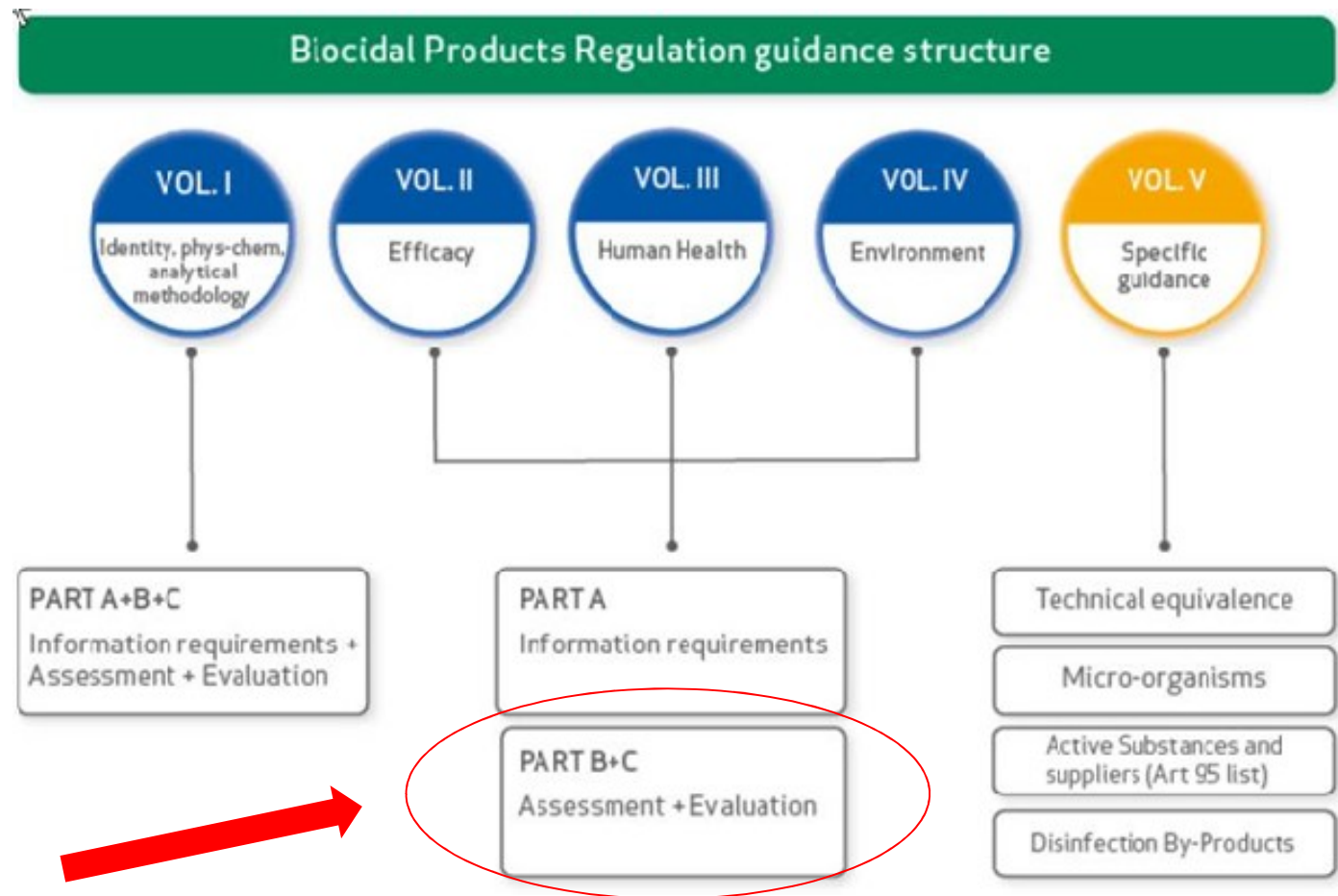
### Other

- ⇒ Antifouling products (21), embalming/taxidermist fluids (22)



## Where to find environment related guidance for biocides? (1)

Guidance webpage:  
**Guidance volumes**



## Where to find environment related guidance for biocides? (2)

ESD webpage:

### ESDs and additional PT related scenarios + calculation sheets

<http://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation/emission-scenario-documents>

ESD per product type

Product Type 1 Human hygiene	
Available Emission Scenario Documents (ESD)	<ul style="list-style-type: none"> <li>ESD for PT 1: Emission scenarios for biocides used as human hygiene biocidal products (EUBEES, 2004) [PDF] [EN]</li> </ul>
Additional PT related documents	<ul style="list-style-type: none"> <li>Workshop on environmental risk assessment for Product Types 1 to 6 [PDF] [EN]</li> <li>Cover note "Workshop on environmental risk assessment for Product Types 1 to 6 [PDF] [EN]</li> </ul>
Calculation sheet	<ul style="list-style-type: none"> <li>Emission Estimation PT 1 [XLSX] [EN]</li> </ul>

## Where to find environment related guidance for biocides? (3)

WG webpage:

### Technical Agreements for Biocides (TAB)

<http://echa.europa.eu/about-us/who-we-are/biocidal-products-committee/working-groups>

#### Working Groups of the Biocidal Products Committee

The Working Groups (WG) of the Biocidal Products Committee (BPC) support the Committee with the preparation of its opinions and contribute to the harmonisation of risk assessment under the Biocidal Products Regulation (BPR).

The following permanent Working Groups have been established by the BPC:

- › Working Group - Efficacy
- › Working Group - Analytical Methods and Physico-chemical Properties
- › Working Group - Human Health
- › Working Group - Environment

The Working Groups carry out scientific and technical peer reviews and consider other relevant scientific and technical questions within the scope of the Biocidal Products Regulation. All Working Groups report to the Committee and the Rules of Procedure of the BPC apply.

In addition to the permanent Working Groups, three Ad hoc Working Groups support the BPC and its permanent Working Groups:

- › Ad hoc Working Group - Human Exposure
- › Ad hoc Working Group - Assessment of Residue Transfer to Food
- › Ad hoc Working Group - Environmental Exposure

#### Composition

**The permanent Working Groups** consist of core members and flexible members. In addition, advisers may accompany members to meetings.

Core members are appointed for a renewable three-year term and each Member State may nominate up to two core members for each Working Group.

#### Working Groups



- › Efficacy
- › Analytical Methods and Physico-chemical Properties
- › Human Health
- › Environment

#### Ad hoc Working Groups



- › Human Exposure
- › Assessment of Residue Transfer to Food
- › Environment Exposure

#### Technical Agreements

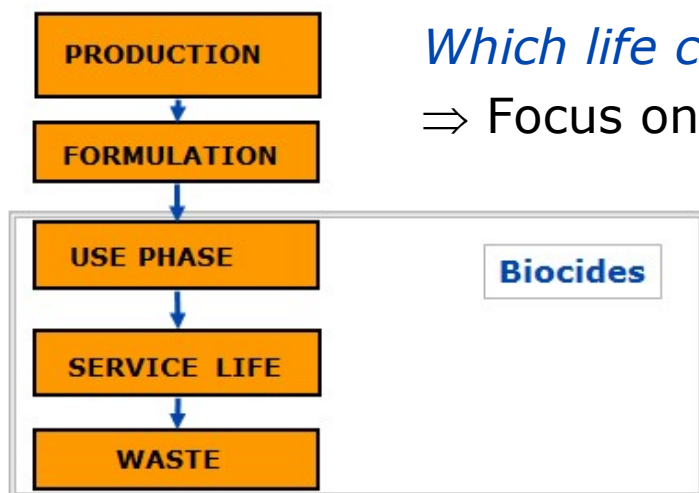


- › Technical Agreements for Biocides [PDF]

# Principles of exposure assessment

*When is an environmental risk assessment needed?*

⇒ Always required for active substance(s), its relevant metabolite(s) and for substances of concern in a biocidal product

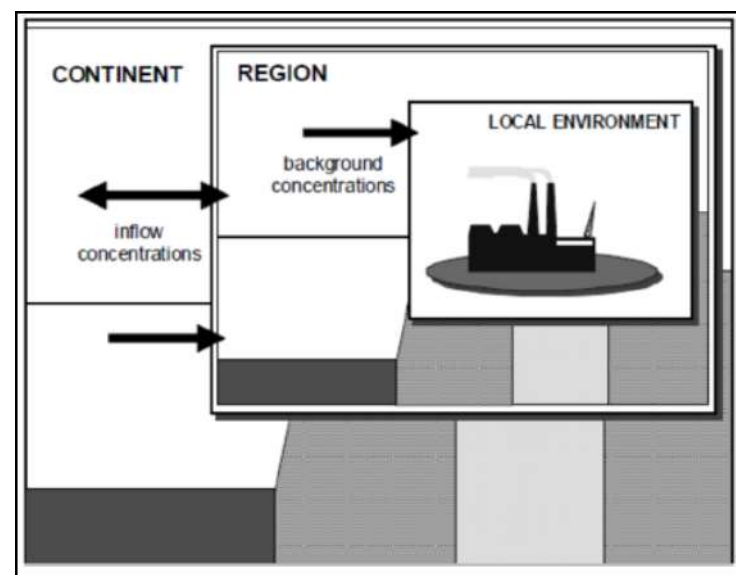


*Which life cycles steps are assessed?*

⇒ Focus on the use phase and service life

*Which scale is considered?*

⇒ Usually only local assessment, quantitative regional assessment to consider background contribution is not routinely performed.





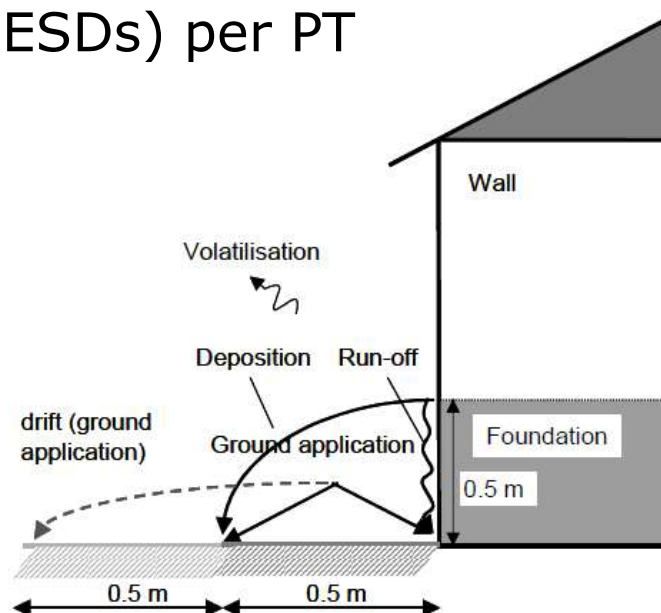
## How is the emission estimation conducted?

### 1. Tonnage based approach

- Based on annual EU tonnage
  - Primarily focused on emission to wastewater
  - Define fraction of tonnage used in standard EU region (Fregion) and standard STP catchment (Fmainsource)
  - Determine daily emission by taking account of number of emission days (T<sub>emission</sub>)
  - Defaults for the potential for environmental release associated with the situation = Emission fractions (air, soil, wastewater, water)
- ⇒ Default parameterisation defined in Product-type specific Emission Scenario Documents (ESDs) for Biocides - or in A- and B- Tables of the EU-TGD

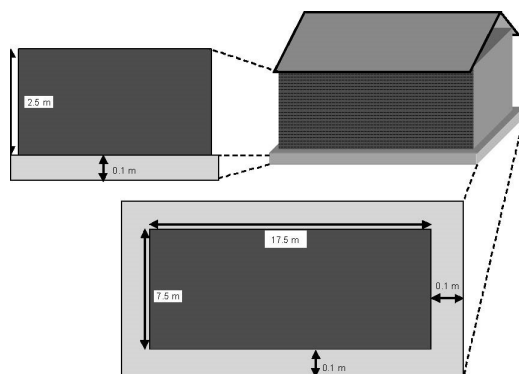
## 2. Application rate/consumption based approach

- Quantity of substance used in a single application or treatment = Application or dose rate x treatment area or volume
- A wide range of different application types exists resulting in a wide range of emission scenarios described in **Emission Scenario Documents (ESDs)** per PT
- Particularly suited to situations where exposure is highly localised: Direct or indirect emission to soil



## .....continued

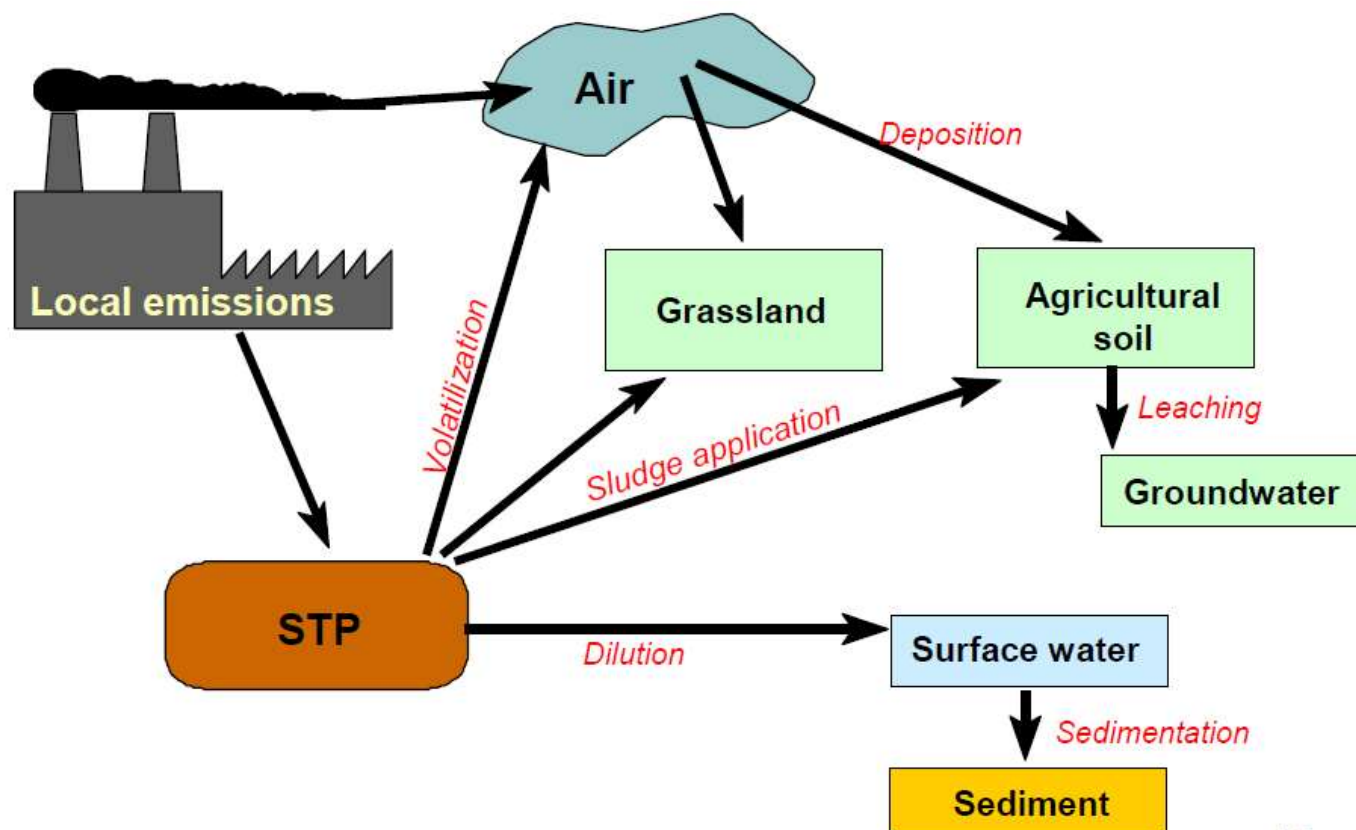
- ESDs provide default treatment areas/volumes or use fractions for the emission estimation:
  - ⇒ Outdoor use of masonry/wood preservatives/paints: Dimensions of external façade (range of scenarios)
  - ⇒ Indoor and outdoor use of insecticides: Area treated (crack & crevice, barrier treatment, ant nest etc.)
  - ⇒ Consumer use of disinfectants/personal care products: quantity used per person per day



Parameters	Nomenclature	Value	Unit	Origin
<b>Input</b>				
Application rate of the active substance	$Q_{a,i,appl}$		$[g \cdot m^{-2}]$	S
Surface area to be disinfected	$AREA_{surface}$			
Slaughterhouses		10,000	$[m^2]$	D
Large scale catering kitchens		2,000	$[m^2]$	D
Number of applications per day	$N_{appl}$	1	$[d^{-1}]$	D
Fraction of substance disintegrated during or after application (before release to the sewer system)	$F_{dis}$	0	$[-]$	D
Fraction of substance eliminated due to on-site pre-treatment of waste water	$F_{elim}$	0	$[-]$	D
Fraction released to wastewater	$F_{water}$	1	$[-]$	D
<b>Output</b>				
Local release to waste water	$E_{local,water}$		$[kg \cdot d^{-1}]$	O
<b>Calculation</b>				
$E_{local,water} = Q_{a,i,appl} \cdot AREA_{surface} \cdot N_{appl} \cdot (1 - F_{dis}) \cdot (1 - F_{elim}) \cdot F_{water} / 1000$				

## Fate & distribution/ Effect assessment / Risk assessment

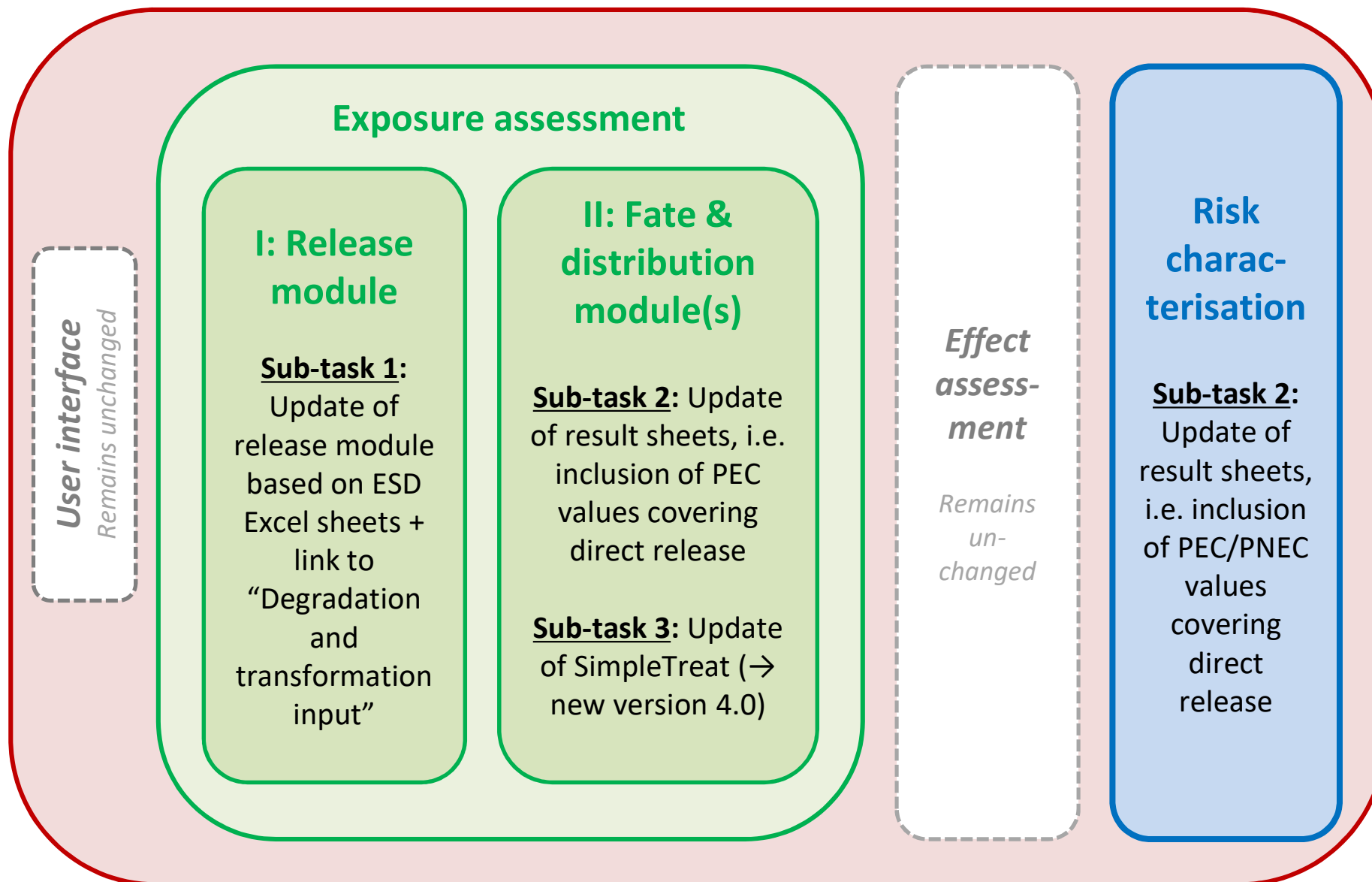
Similar principles as under REACH (+ direct release)



## Biocides in EUSES

- Specific assessment of biocides on local scale for biocides implemented in EUSES
  - Emission scenarios according to PT specific ESDs
  - Consumption and tonnage based approach
- Developments/revisions after 2012 not implemented (i.e. 6 Biocide Emission Scenario Documents + several single emission scenarios)
- Intermediate solutions
  - ESD calculation sheets covering new ESDs + revised and new emission scenarios (see ESD related ECHA webpage: <https://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation/emission-scenario-documents>)
  - EUSES „quick fix“ => EUSES v.2.2.0 (Q4 2018/Q1 2019)

# EUSES quick fix: Sub-tasks 1 to 3



# Thank You.... Any Questions?

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The above represents the opinion of the author and is not an official position of the European Chemicals Agency.