
Expositionsabschätzung und Erstellung von Expositionszenarien

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- Ablauf einer Expositionsabschätzung
 - Szenarienerstellung
 - Expositionsabschätzung
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- Was kann schief gehen?

Expositionsszenario

- **Exposition:** „Im Sinne des Arbeits- und Verbraucherschutzes bedeutet es, dass Menschen mit einem Stoff in Kontakt kommen. Umweltexposition bedeutet, dass Stoffe in die Umweltmedien Luft, Oberflächenwasser, Boden und Grundwasser gelangen und ihnen die dort lebenden Organismen ausgesetzt sind.“
- **Expositionsszenarium** nach REACH Artikel 3 Nr. 37: "Zusammenstellung von Bedingungen, mit denen dargestellt wird, wie der Stoff hergestellt oder während seines Lebenszyklus verwendet wird und wie der Hersteller oder Importeur die Exposition von Mensch und Umwelt beherrscht oder den nachgeschalteten Anwendern zu beherrschen empfiehlt. Diese Expositionsszenarien können ein spezifisches Verfahren oder gegebenenfalls verschiedene Verfahren oder Verwendungen abdecken".

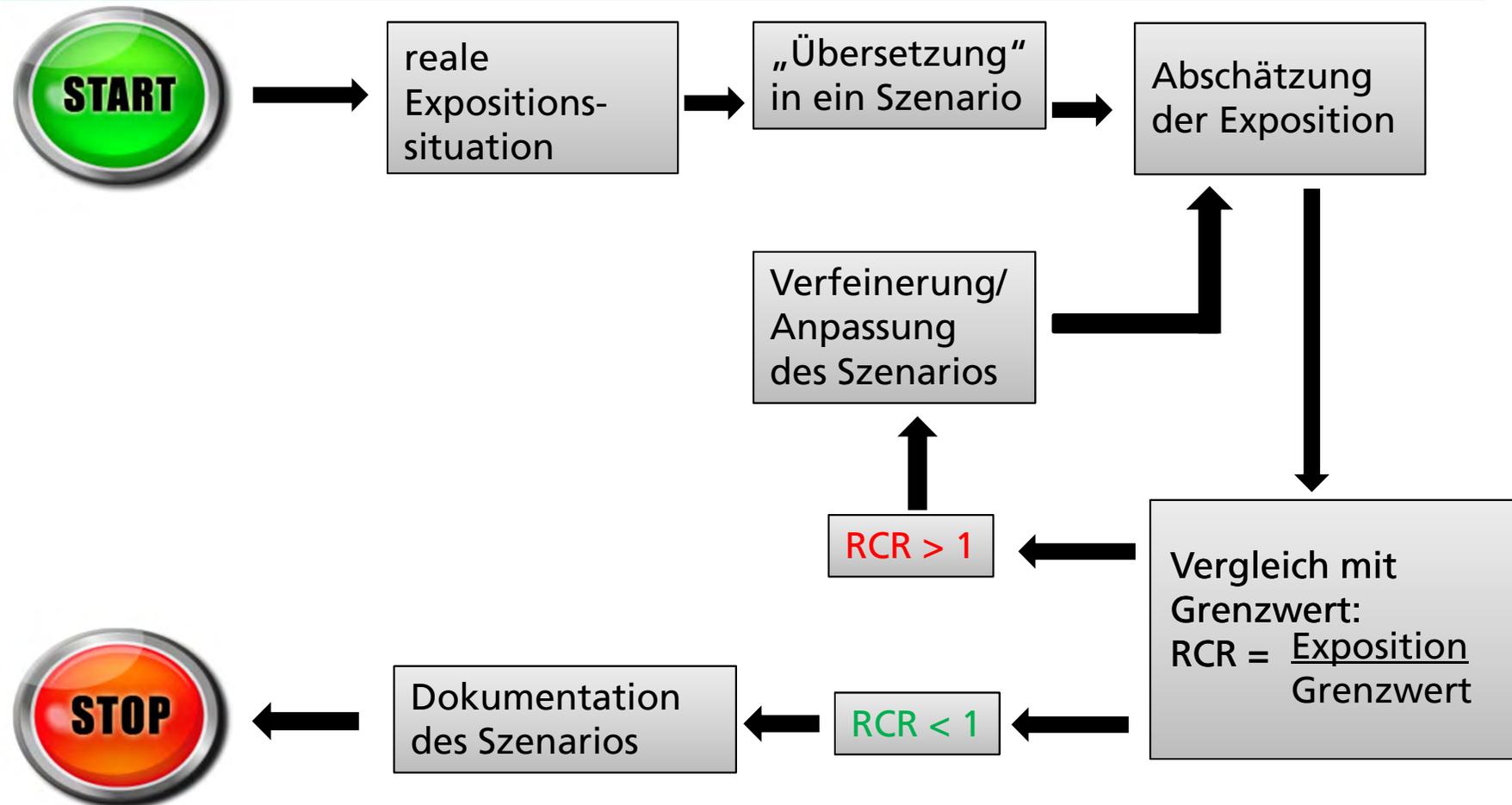


Sichere Herstellung und Anwendung der Substanz soll sicher gestellt werden

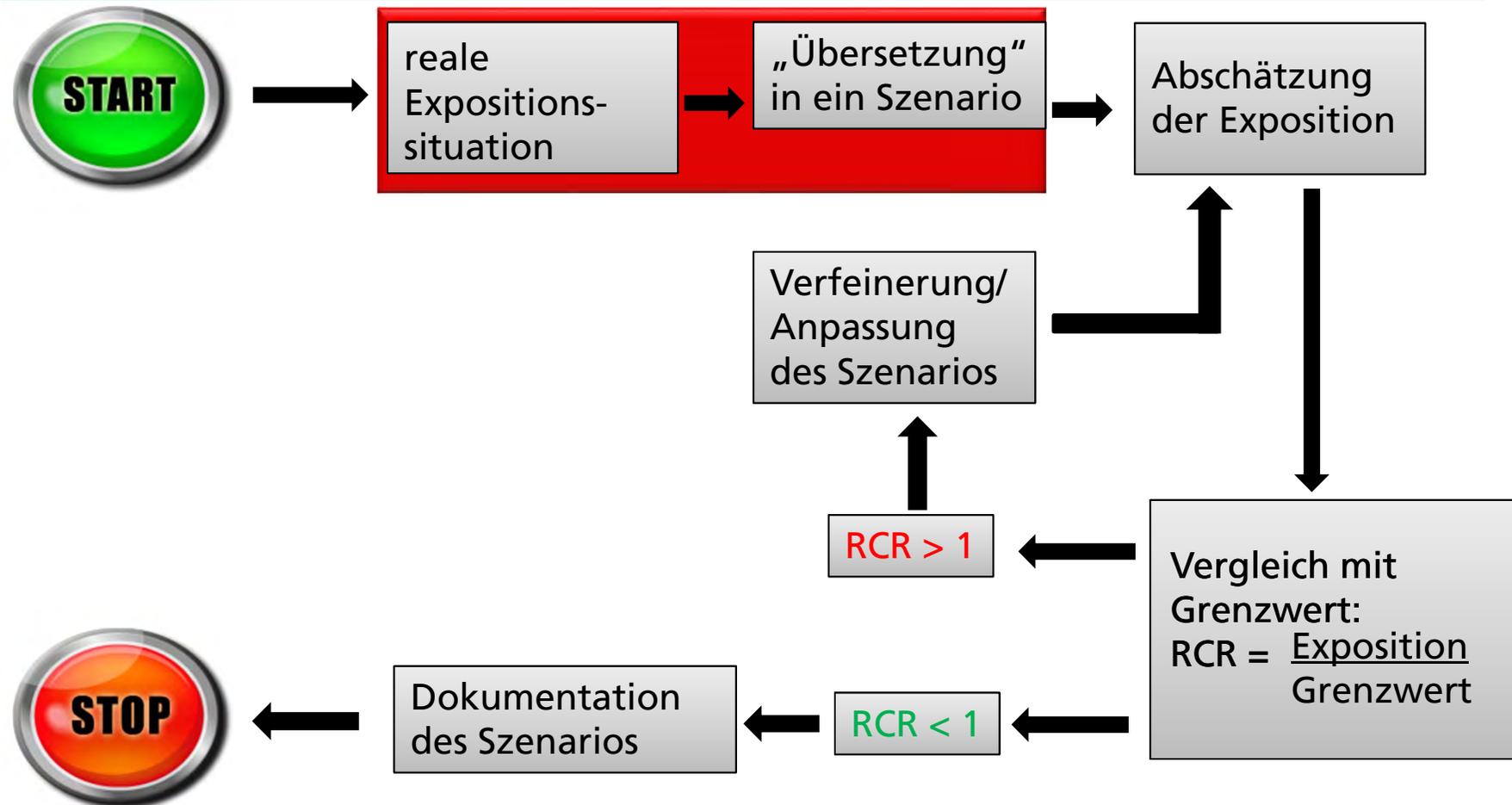
Exposition im Sicherheitsdatenblatt

- Expositionsabschätzung und Risikobeschreibung ist nötig, wenn...
 - ... der Stoff in Tonnagen > 10 t/a importiert oder hergestellt wird
 - ... der Stoff gefährlich ist (Artikel 14(4))
 - ... der Stoff die PBT/vPvB Kriterien erfüllt
 - Expositionsszenarien im eSDS müssen mit denen im CSR übereinstimmen
- Annex: Liste von Expositionsszenarien

Exposition: Szenario vs. Abschätzung



Exposition: Szenario vs. Abschätzung



Exposition: Szenario

- **Allgemein: Szenarien für Mensch und Umwelt**

- Kurzer **Titel**/Textbeschreibung der Tätigkeit

- **Risikominimierungsmaßnahmen:**

- Umweltszenario: Spezifikationen der Kläranlage, Anteil Substanz der emittiert wird, Luftfilter,...

- Humanexposition: Ventilation, geschlossenes System, ...

- **Persönliche Schutzausrüstung:**

- Humanexposition: Handschuhe, Atemschutz ...

Exposition: Szenario

■ **Anwendungsbedingungen:**

- Umweltexposition: Zahl Emissionstage pro Jahr, Tonnagen, ...
- Humanexposition: Anwendungsdauer und -frequenz, Konzentration der Substanz ...

■ **Effizienzen** der beschriebenen Schutzmaßnahmen

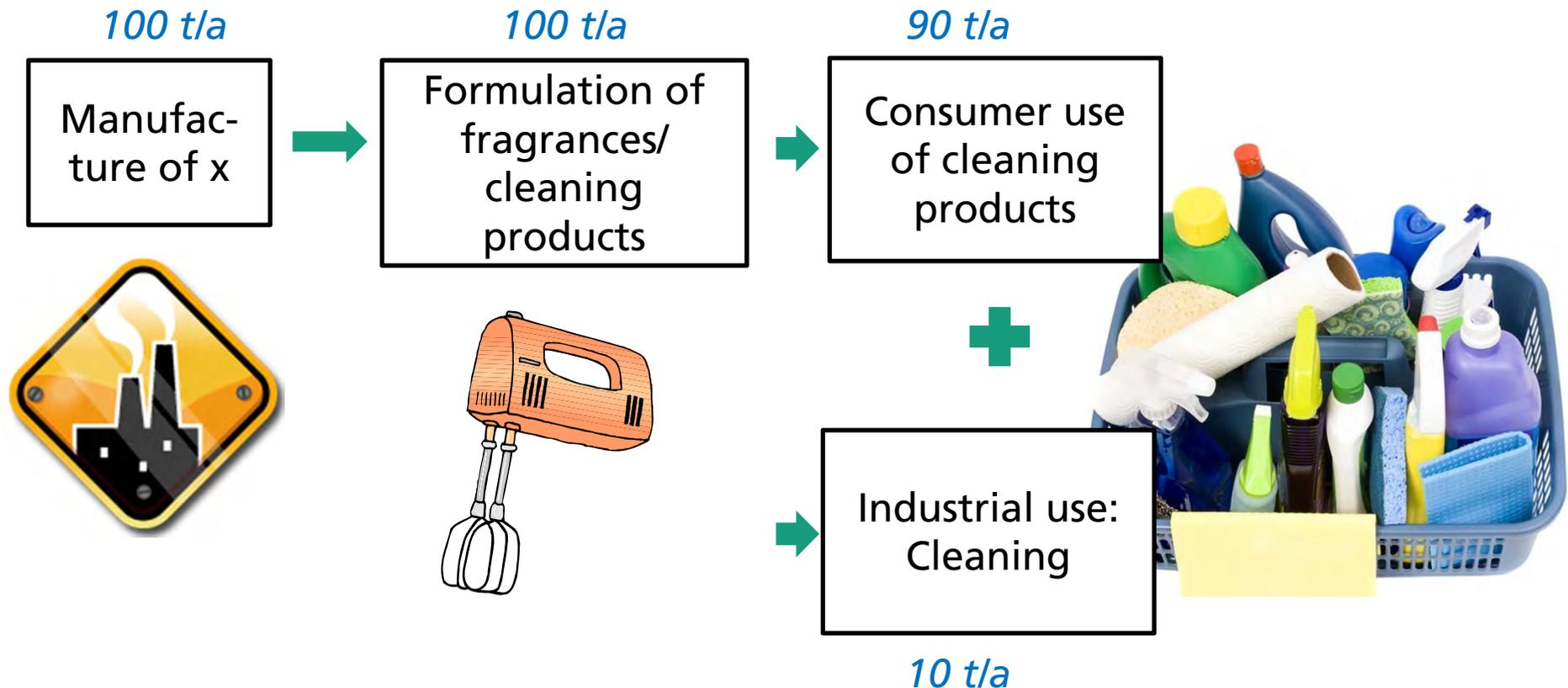
Exposition: Szenario

Beschreibung des Szenarios:

- Deskriptorsystem (Guidance R12) wird empfohlen:
 - **SU** = Sector of use/industry, z.B. SU8/9 Manufaktur von Chemikalien
 - **ERC** = Environmental release category, z.B. ERC2 Formulierung (Umwelt -> Guidance R16)
 - **PROC** = Process category, z.B. PROC5 Mischen (Arbeiter -> Guidance R14)
 - **PC** = Product category, z.B. PC35 Reinigungsprodukte (Marktsektor, Konsument -> Guidance R15)
 - **AC** = Article category, z.B. AC8 Papierprodukte (Konsument -> Guidance R15)
 - s.a. Guidance R17 (articles), R18 (waste life stage), R13 (risk management measures and operational conditions)

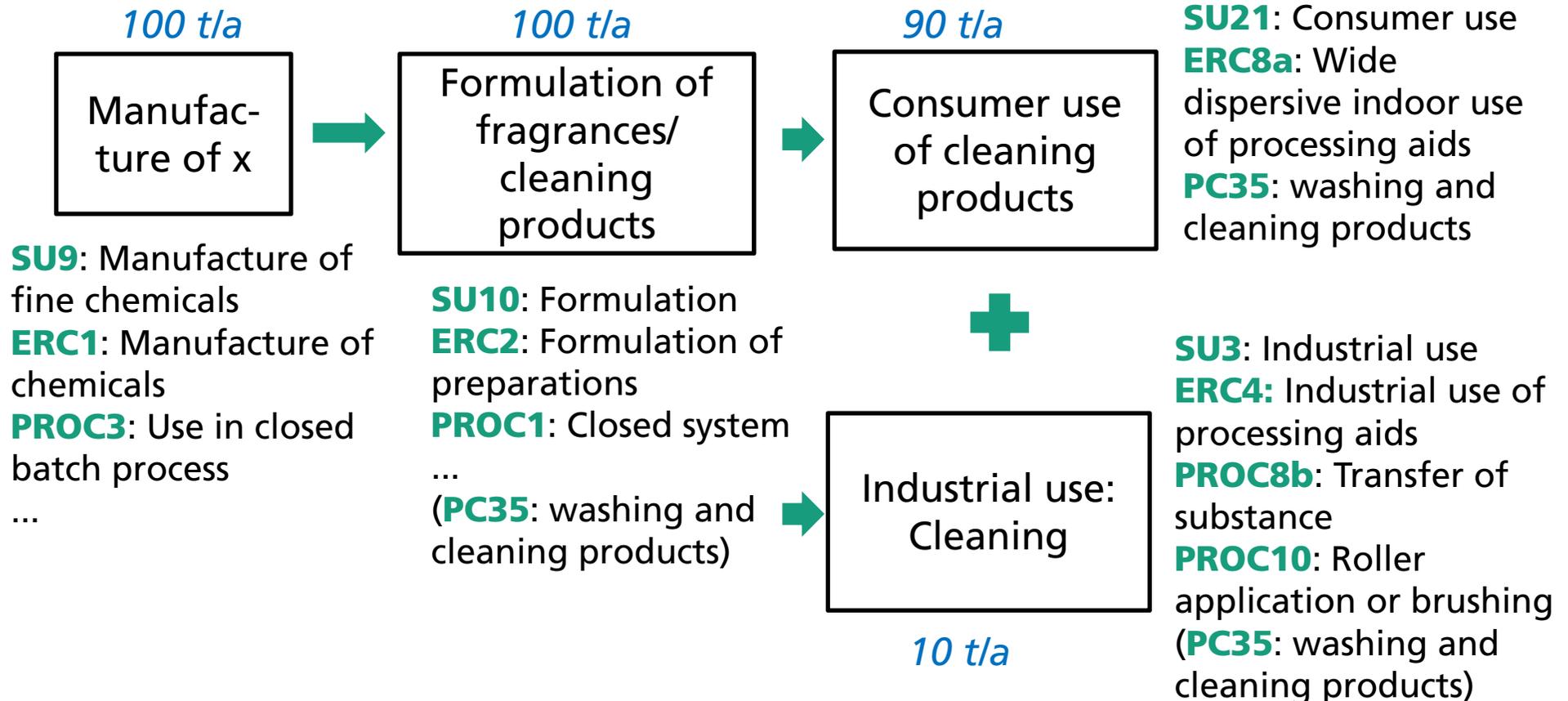
Exposition: Szenario

- Alle Stufen des Lebenszyklus' sollen mit Szenarien beschrieben werden
- Teilweise werden Szenarien von Verbänden bereit gestellt (z.B. CEPE, A.I.S.E.)

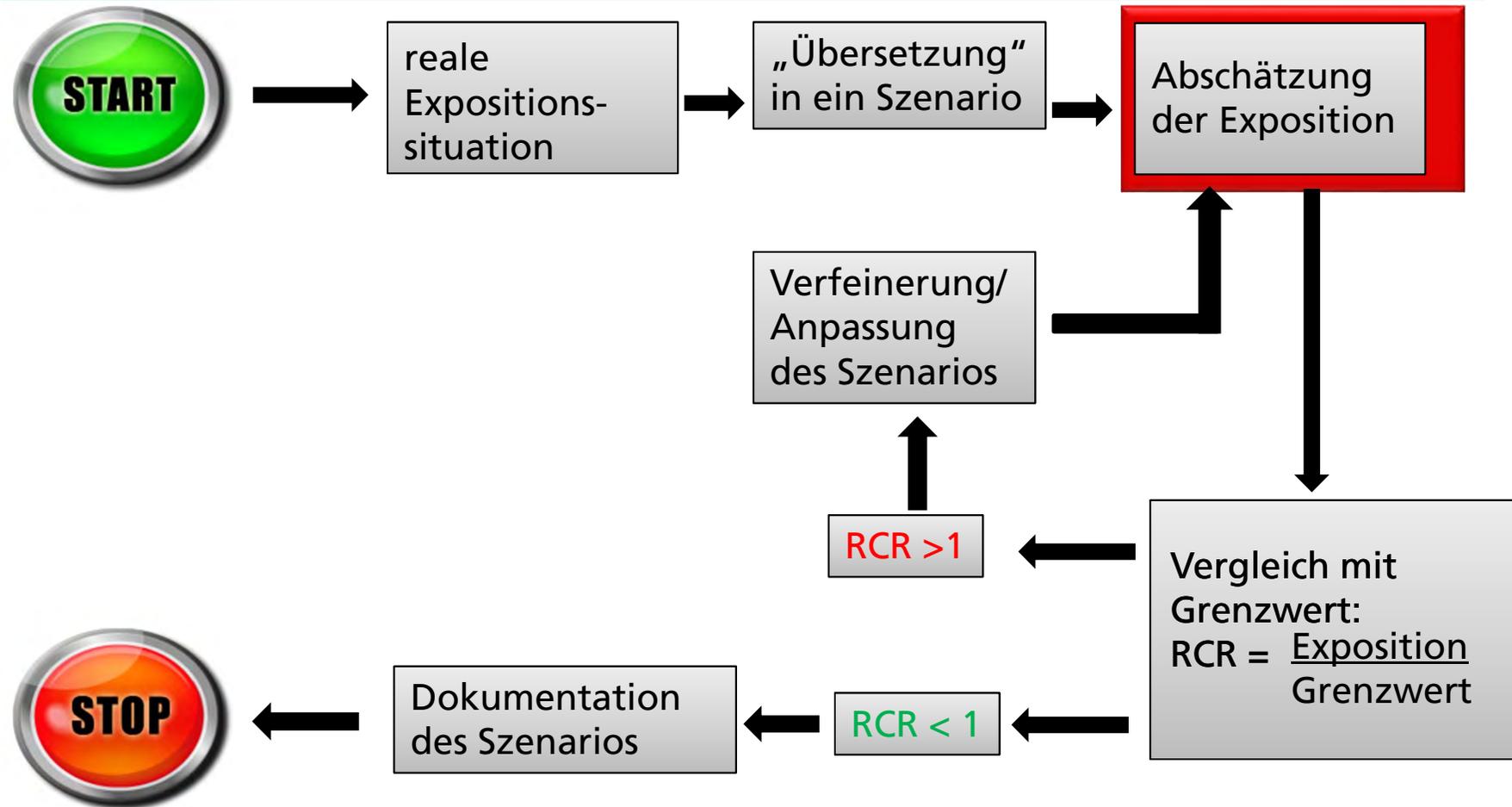


Exposition: Szenario

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Exposition: Szenario vs. Abschätzung



Exposition: Abschätzung Tier 1

Beispiel ECETOC TRA v.3

Physical-chemical properties - minimum input for Human Health and Environmental Assessment

| | |
|-----------------------------------------------------|-------------------------|
| Molecular weight | 123 g.mol ⁻¹ |
| Vapour pressure (Pa OR hPa) | 5.00E-02 Pa |
| Water solubility | mg.L ⁻¹ |
| Partition coefficient octanol-water (- OR Log(Kow)) | Kow |
| Biodegradability test result | |
| Chemical class for Koc-QSAR | |
| Koc (L.kg ⁻¹) OR Log(Koc) | Koc |
| Partition coefficient k_{ow} | L.kg ⁻¹ |
| Partition coefficient k_{ow} | L.kg ⁻¹ |
| Partition coefficient to suspended solids | L.kg ⁻¹ |

Additional physico-chemical parameter input for refined environmental assessment (TIER 2)

- Tier 1: Einfach, kategorisierend
- Deskriptoren (ERC/PROC/PC) + Grundlegende Anwendungsinformation
- Basisinformationen Substanz (Dampfdruck/ Staubigkeit, Wasserlöslichkeit, ...)
- Grenzwerte

Arbeiter: z.B. PROC3, type of setting, Konzentration, Dauer, Ventilation, Atemschutz, Handschuhe

| Process Category (PROC) | Type of setting (PROC 7 and 22 always industrial, PROC 11 and 20 always professional) | Is substance a solid? (yes/no) | Dustiness of solids OR VP of volatiles (Pa) at process temperature (clear entries if you change column F to "No") | Duration of activity [hours/day] | Use of ventilation? (addresses outdoor use, LEV and general ventilation) | Use of respiratory protection and, if so, minimum efficiency? |
|-------------------------|------------------------------------------------------------------------------------------|--------------------------------|----------------------------------------------------------------------------------------------------------------------|----------------------------------|-----------------------------------------------------------------------------|---------------------------------------------------------------|
| PROC 1 | industrial | No | | >4 hours (default) | Indoors | No |
| PROC 2 | industrial | No | | >4 hours (default) | Indoors | No |
| PROC 3 | industrial | No | | >4 hours (default) | Indoors | No |

Exposition: Abschätzung Tier 1

Beispiel ECETOC TRA v.3

Konsument: z.B. PC35, Unterkategorie

| Product / Article category | PC / AC sub-category (optional for calculating subcategory outcomes) | For PC only: Is product a spray? | Amount of product used per application (g) | Product ingredient fraction by weight (value must be: 0 < [value] < 1) | Skin surface area - dermal |
|---------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------|----------------------------------|--------------------------------------------|------------------------------------------------------------------------|----------------------------|
| PC35_Washing_and_cleaning_products_including_solvent_based_products | Cleaners, liquids (all purpose cleaners, sanitary products, floor cleaners, glass cleaners, carpet cleaners, metal cleaners) | | | | |

Umwelt: z.B. ERC2, Tonnage (Tonnage to region, STP)

| Annual EU Tonnage (tonnes/year) | Fraction of tonnage to region (for ERCs 1-7 and 12a,12b = 1, ERC 8-11b = 0.1)* | Use ERC or spERC as release estimation approach (default is ERC) | ERC (mandatory in all cases as use descriptor !) | STP for ERC (default is Yes, unless for ERC 1-7 and 12a, 12b direct discharge is given) |
|---------------------------------|--------------------------------------------------------------------------------|------------------------------------------------------------------|--------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1.00E+02 | | ERC | ERC2 | |

→ sowohl Arbeiter-, als auch Konsumenten- und Umweltexposition können grob geschätzt werden

Exposition: Abschätzung

EMKG - Exposure assessment part for liquids



| Definition of volatility bands | | | Alternative input of | |
|--------------------------------|------------------------------------|--------------------------------|---------------------------------------------------|------------|
| Band | At normal temperature (-20°C) | Operating temp. (o.t.) | boiling point (°C) and operating temperature (°C) | |
| Low | boiling point above 150°C | b.p. $\geq 5 \times o.t. - 50$ | <input type="text"/> °C | |
| Medium | boiling point between 50 and 150°C | other cases | <input type="text"/> °C | |
| High | boiling point below 50°C | b.p. $\leq 2 \times o.t. + 10$ | input b.p. | input o.t. |

| Scale of use bands | | Short term exposure | | Applications on surfaces > 1m ² | |
|----------------------|--|--------------------------------------------------|----|-------------------------------------------------------------------------------------|----|
| <input type="text"/> | | Activity ≤ 15 min. during a full 8 h shift? | | e.g. painting, applying adhesives etc. and more than 1 litre product used per shift | |
| <input type="text"/> | | Yes | No | Yes | No |

Andere Beispiele:

Arbeiter:

- EMKG-Expo-Tool
- Stoffenmanager
- RISKOFDERM
- MEASE
- ART (Advanced Reach Tool)

Umwelt:

- EUSES

Konsument

- Consexpo

Risk assessment inhalation

+ explanation

Name: 100%benzol in Aceton liquid
 Department: test
 Product: Benzol100% in Aceton
 Dilution: 100
 Task: Handling of liquids in tightly closed containers

+ Step 1 of 4

+ Step 2 of 4

Duration task: 1 to 30 minutes a day
 Frequency task: 1 day a year

Duration task: when you perform a task more than once a day, please estimate the total time on a working day spent on performing the task (example: you perform a task 4 times a day, the task takes 10 minutes on average; this amounts to 40 minutes over the working day; choose the category 0,3 -2 hours a day).

Is the working room being cleaned daily? yes no

Are inspections and maintenance of machines/ancillary equipment being done at least monthly to ensure good condition and proper functioning and performance? yes no

+ Step 3 of 4

+ Step 4 of 4 - Risk assessment

Save Cancel

Give a name to the assessment if you want to:

Choose the relevant process for the assessment

| | | |
|----------------------------|--------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Filling, mixing or loading | Filling, mixing or loading refers to: | weighing of powders, dumping of powders from bags or drums, pumping of liquids, pouring of liquids, scooping of liquids or pastes, etc. the purpose is to transfer product from one container to another |
| Wiping | Wiping refers to: | wiping surfaces with a liquid (preparation), including e.g. cleaning agents. wiping is done with a sponge or cloth or rag, or another tool without handle. the purpose is to spread the product over the surface |
| Dispersion hand-held tools | Dispersion with hand-held tools refers to: | dispersion of products or substances by using a brush, comb, rake, roller or other tool with a handle. the purpose is to spread the product over a surface |
| Spraying | Spraying refers to: | spray application of products such as paints, glues, cleaning agents. hosing down with water using a normal water line under normal pressure is not included. |
| Immersion | Immersion refers to: | immersing objects in chemicals, where the exposure is to the chemicals in which the product is immersed and not to substances coming from the object. |
| Mechanical_treatment | Mechanical treatment refers to: | treatment of solid objects leading to emission of substances. This relates to substances emitted from the solid objects, e.g. wood dust, but also to substances used in the process of treatment, e.g. metal working fluids. |

Exposition: Abschätzung

Andere Beispiele:

Arbeiter:

- EMKG-Expo-Tool
- Stoffenmanager
- RISKOFDERM
- MEASE
- ART (Advanced Reach Tool)

Umwelt:

- EUSES

Konsument

- Consexpo

MEASE 1.02.01
Exposure Assessment Tool
For Metals And Inorganic Substances

© 2009, 2010 EBRC Consulting GmbH
D. Vetter
Hannover, Germany

| Model parameters | R | Exposure modifier |
|------------------------------------------|---|------------------------------------------|
| 20000 | | --- |
| Solid, low dustiness | | --- |
| > 25% | | Low fugacity (dustiness based) |
| | | 100% |
| ances bound in materials and/or articles | | --- |
| Industrial use | | --- |
| > 240 minutes | | Industrial use |
| | | 100% |
| Closed system without breaches | | Low dermal exposure potential |
| Non-direct handling | | Low dermal exposure potential |
| None | | Low dermal exposure potential |
| LEI (generic) | | 18% |
| Median estimate | | (as reflected in reduction factor above) |
| No RPE | | 100% |
| No gloves | | 100% |
| | | Exposure estimate |
| | | 0.5 µg/cm ² /day |
| | | 1980 cm ² |
| | | 0.99 mg/day |
| | | 0.99 mg/m³ |

Release fractions and emission days [1 "", IC=15/UC=55]

Industrial use

Emission tables: A3.16 (general table), B3.14 (general table)

Release fractions

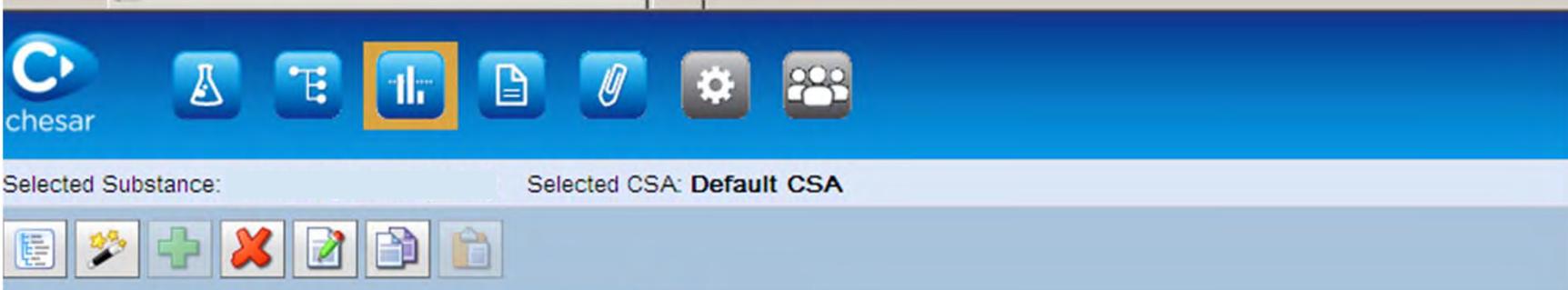
| | | | |
|---------------------------------------------------|-------|-----|---|
| Fraction of tonnage released to air | 1 | [-] | o |
| Fraction of tonnage released to wastewater | 0 | [-] | o |
| Fraction of tonnage released to surface water | 0 | [-] | o |
| Fraction of tonnage released to industrial soil | 5E-03 | [-] | o |
| Fraction of tonnage released to agricultural soil | 0 | [-] | o |
| Emission fractions determined by special scenario | No | | o |

Emission days

| | | | |
|----------------------------------------------|-----|-----|---|
| Fraction of the main local source | 0.1 | [-] | o |
| Number of emission days per year | 20 | [-] | o |
| Release to wastewater only | No | | d |
| Emission days determined by special scenario | No | | o |

Prev Next Finish Undo Abort Help

Exposition: Abschätzung Tier 1



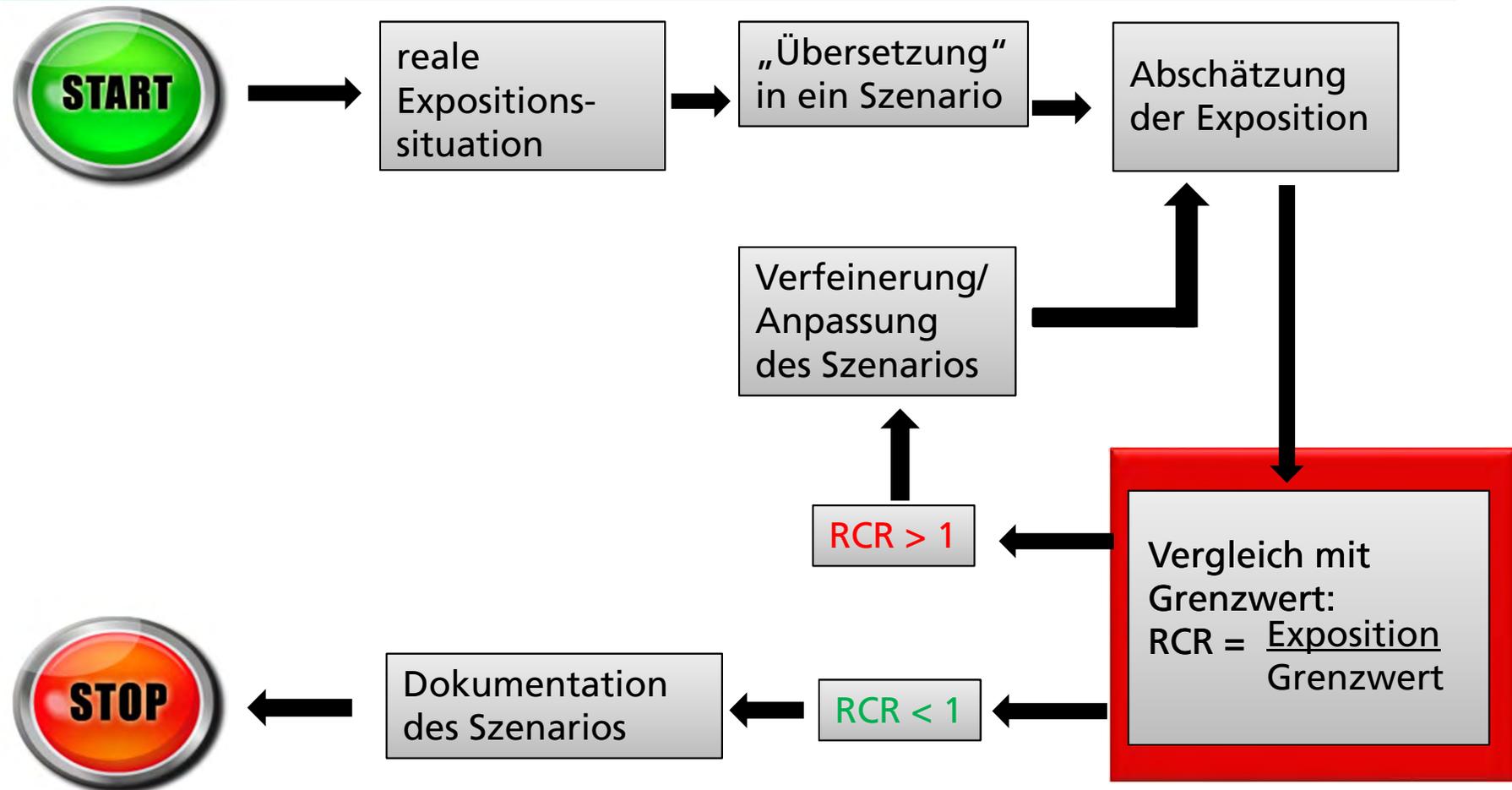
The screenshot shows the Chesar software interface. At the top, there is a blue header with the 'chesar' logo and several icons: a flask, a network diagram, a bar chart (highlighted with a yellow box), a document, a paperclip, a gear, and a group of people. Below the header, it displays 'Selected Substance:' and 'Selected CSA: Default CSA'. A toolbar contains icons for document, search, add, delete, edit, print, and save. The main area shows a project tree with the following items:

- Combined Environmental Assessment
 - Releases
- Market (273.0 t) Products such as ph-regulators, flo...
- Formul. (91.0 t) ERC 2: Formulation of wor
 - ERC 2: Formulation of working solution
 - EUSES
 - PROC 3: Use in closed batch process (F
 - PROC 3: Use in closed batch process (F
 - PROC 4: Use in batch and other process
 - PROC 4: Use in batch and other process
 - PROC 8b: Transfer of substance or prep
 - PROC 8b: Transfer of substance or prep
 - PROC 8: Transfer of substance or prep

Chesar

- ECETOC TRA Algorithmus ist implementiert → direkter Export von CSR und (langfristig) SDS möglich
- Auch für andere Tools Implementierung geplant (z.B. MEASE, Stoffenmanager, EMKG-Expo)

Exposition: Szenario vs. Abschätzung



Risiko – und nun?



1. Verfeinerung des Szenarios:

Humanexposition

- Nutzungsbedingungen, Aufnahme des Stoffes in den Körper, nicht berücksichtigte RMMs...
- eventuell andere Tools, Informationsbeschaffung, Literatursuche

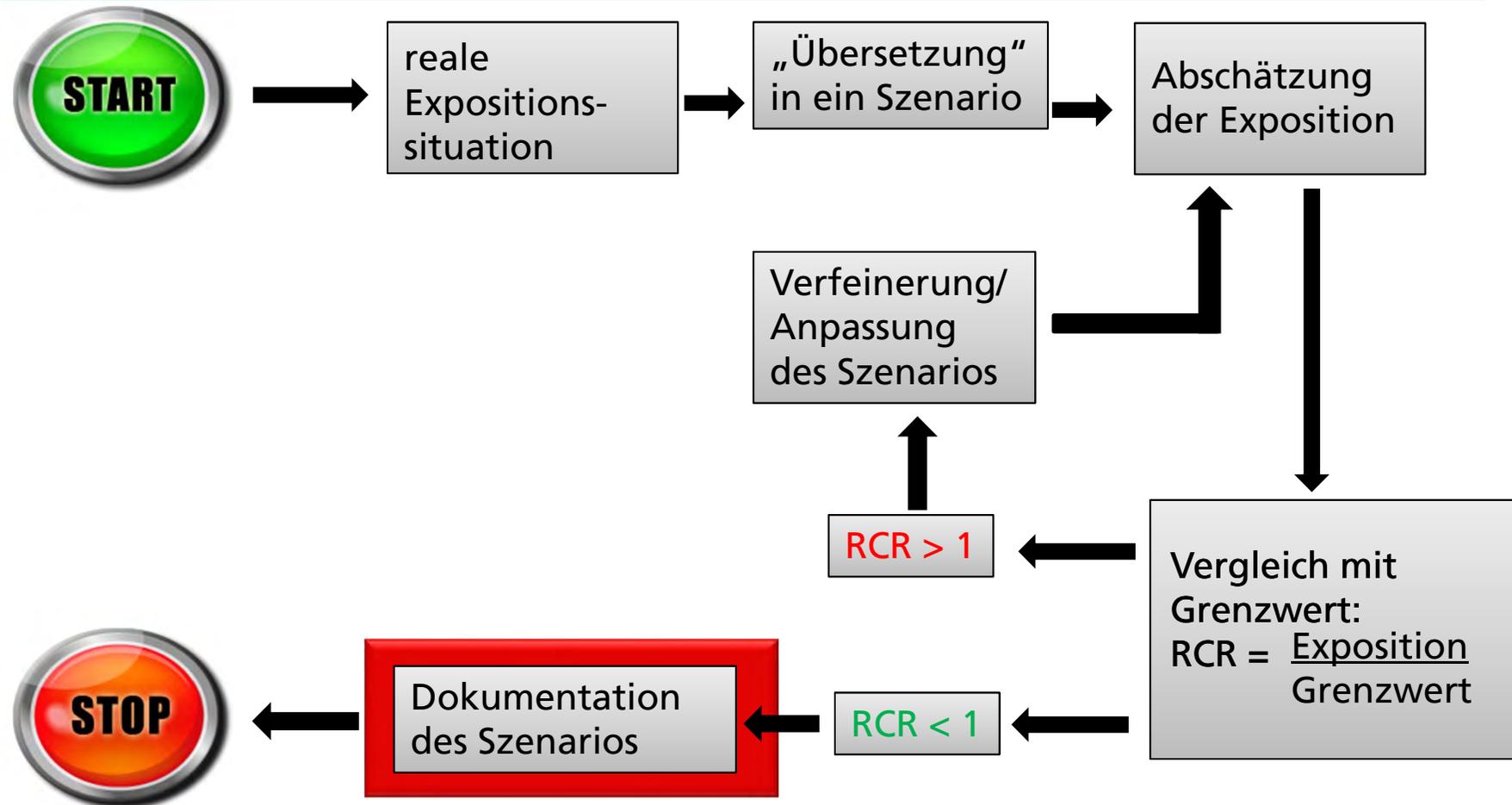
Umweltextposition

- Nutzungsbedingungen, nicht berücksichtigte RMMs...
- SpERC (specific environmental exposure category)

2. Messung der Exposition

3. Anpassung der realen Situation

Exposition: Szenario vs. Abschätzung



Dokumentation → Schritt „Szenarienerstellung“

- Kurzer **Titel**/Textbeschreibung der Tätigkeit

- **Risikominimierungsmaßnahmen:**

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Dokumentation → Schritt „Szenarienerstellung“

- **Effizienzen** der beschriebenen Schutzmaßnahmen

- **Ergebnisse:**

- Expositionswerte für Arbeiter und Konsument für alle relevanten Routen (inhalation, dermal, evt. oral)
- Expositionswerte für Umweltkompartments (Meer, Süßwasser, Erde, Kläranlage)
- Wie ist man zu den Ergebnissen gekommen (Tools, Annahmen etc.)
- Vergleich mit zugehörigen Grenzwerten (DNEL, PNEC), z.B. als Risk Characterisation Ratio
- Ggf. Angabe einer zulässigen Maximalmenge (M_{safe})

Zusätzliche Hilfen: Scaling-Tools

- Einfache Tools zur Anpassung eines sicheren Szenarios auf Basis der existierenden
- Werden vom Registranten zusammen mit der Expositionsabschätzung zur Verfügung gestellt
- Insbesondere für Umweltexposition (Wasserkontamination, seltener Erde)
- Verschiedene Tools

| Step | Parameter | Standard Input | User input | Considered Parameter |
|------|---------------------------------------------------------------------|----------------|------------|----------------------|
| 0 | PNEC surface water (µg/L) | 20 | | 20 |
| | PNEC sediment surface water (mg/kg dwt) | 1.1 | | 1.1 |
| | PNEC STP (mg/L) | 3.16 | | 3.16 |
| 1 | Background level water (µg/L) | 3.47 | | 3.47 |
| | maximum Conc. water, local (µg/L) | 16.53 | | 16.53 |
| 2 | Reduction rate of the STP (%) ** | 7.72 | | 7.72 |
| | Dilution (max. 1000 possible) | 10 | | 10 |
| 3 | Effluent discharge rate of the sewage treatment plant (m³/d) | 2000 | | 2000 |
| 4 | Flow rate of the river (m³/d) | 18000 | | 18000 |
| 5 | Effluent discharge rate of your industrial plant (m³/d) | 2000 | | 2000 |
| | Concentration in wastewater after the STP (mg/L) | | | 0.165 |
| | Concentration untreated wastewater (after dilution at STP) (mg/L) | | | 0.179 |
| | Concentration untreated wastewater (directly after site) (mg/L) | | | 0.179 |
| | Release into waste water after on site waste water treatment (kg/d) | | | 0.36 |
| 6 | Release fraction of the chemical (%) | 100 | | 100 |
| 7 | Environmental Release Class ERC* | | ERC 4 | ERC 4 |
| 8 | Release time (d/y) | 10 | 20 | 20 |
| | Acceptable Use volume water (t/a) | | | 0.007 |
| | Acceptable Use volume sediment (t/a) | | | 0.007 |
| | Acceptable Use volume WWTP (t/a) | | | 0.137 |
| | Acceptable use volume (t/a) | | | 0.007 |

Was kann schief gehen?

■ Anwendungsrahmen der Tools beachten

- ➔ Tier 1 = einfach, kategorisierend
- ➔ Modellhintergrund: Gemessene Werte, Expert Judgement, Gleichungen?
- ➔ deckt das Tool meine Substanz und mein Szenario ab?
 - ➔ Raumentwicklung: Nicht abgedeckt z.B. von ECETOC TRA, EMKG-Expo, Stoffenmanager
 - ➔ Inhalation flüssiger Aerosole: Nicht abgedeckt z.B. von EMKG-Expo, ECETOC TRA, ...
 - ➔ exponierte Hautareale: manche Tools betrachten nur Hände/Unterarme (z.B. ECETOC TRA, MEASE)

Was kann schief gehen?

■ Validierungsstatus?*

■ **Kommunikation!**

- ➔ Use Mapping
- ➔ Keine korrekte Zuordnung von Deskriptoren und Parametern
- ➔ Beliebtes Beispiel: PROC 19: Hand mixing



| of Use | Process Category | Chemical Product Category |
|-------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------|----------------------------------------------------------------|
| 3, 4, 5, 6, 9, 10, 12, 16, 17, 18, 19, 20, 21, 22 | 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 17, 18, 19, 20, 21 | 1, 3, 5, 9, 10, 15, 17, 18, 24, 25, 26, 28, 31, 32, 34, 35, 39 |
| Article Category | Environmental Release | |
| 1, 2, 3, 5, 8, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 34, 35, 36, 37, 38, 39 | 2, 3, 4, 5, 6A, 6B, 6C, 6D, 7, 8A, 8B, 8C, 8D, 8E, 8F, 9A, 9B, 10A, 10B, 11A, 11B | |

Vielen Dank für Ihre Aufmerksamkeit!



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Tools für die Expositionsabschätzung

ECETOC TRA:

<http://www.ecetoc.org/tra>

Chesar:

<http://chesar.echa.europa.eu/>

EMKG-Expo:

<http://www.reach-clp-helpdesk.de/en/Exposure/Exposure.html>

Stoffenmanager:

<https://www.stoffenmanager.nl/>

RISKOFDERM:

http://www.tno.nl/downloads/RISKOFDERM%2520potential%2520dermal%2520exposure%2520model%2520vs%25202.1t.xls&sa=U&ei=Q9oIUdbJDon4sgawnYCYDA&ved=0CBcQFjAA&usq=AFQjCNEN51jdEtSo_lxbSDtmLWg6FITFtg

MEASE:

<http://www.ebrc.de/industrial-chemicals-reach/projects-and-references/mease.php>

ART:

<https://www.advancedreachtool.com/>

EUSES:

http://ihcp.jrc.ec.europa.eu/our_activities/public-health/risk_assessment_of_Biocides/euses

Consexpo:

<http://www.consexpo.nl>