

**Work Package 2 “Identification of relevant target substances in BREFs”
of the HAZBREF project funded by Interreg Baltic Sea Region**

Report of HAZBREF WP 2 – Annex 6b
Approaches for a better use of chemicals data

**Guidance and Detailed Description:
Interactive Scheme to Identify
Relevant Target Substances**

1 The interactive scheme step-by-step: Block 1: establish chemicals inventory

By using the interactive scheme, the plant operator, (branch association or TWG) is supported in the following steps in the Block 1:

The following decisions and activities are recommended for installation operators. A full list of substances used and information on the processes where the substances are used, is helpful information for branch associations and the TWG too, and they should carry out the activities themselves or support other stakeholders.

B 1: The Block begins with a yellow circle: Block 1 – Establish and / or complete chemicals inventory. The user is asked to draw up a complete inventory of the substances that are used in his installation. A suggestion for the structure of an inventory can be found either by clicking on the symbol in the IT solution or in chapter 5.3.1 of this report. The arrow from B 1 leads to the first question D 1.1.

D 1.1 Improve list of chemicals used in a chemicals inventory

D 1.1: “Are all substances used in the installation recorded in a chemicals inventory? And is process-relevant information available for these substances? For branch associations or TWG: Are all substances used in a sector known and information stored appropriately?” The installation operator often knows the products used but, hardly all the substances in these products. The same may apply to branch associations or TWG. However, information necessary for the safe use of a substance, like substance properties, recommendations for elimination, BATs can only be identified for individual substances. According to REACH, the plant operator is obliged to do so anyway. In the chemicals inventory the data is stored substance-specific. The user can answer the question D 1.1 with Yes or No and is directed to the next question D 1.2 or to the action A 1.1.

A 1.1: If the user answers the question in D 1.1 with No the arrow directs to the action A 1.1: “Apply one or more strategies to complete the list of substances used and associated process information”. By clicking on the symbol in the IT-solution several strategies are suggested to complete the list of substances used and associated process information: strategies A, B, and D developed in the WP 2, SDS, ERCs, SPERCs, and SPIN database. In the strategies A, B and D, various methods are proposed to the user to get an overview of the substances used in an industry. The strategies are mainly applicable for users from branch associations or TWG as the installation operator might not have sufficient knowledge. Nevertheless, branch association should support the operators in compiling a full list of substances used. The basis for the safe use of substances are the safety data sheets, which according to REACH may contain so-called exposure scenarios. Often ERCs or SPERCs are used for exposure assessment according to REACH. SPERCs in particular can contain process-specific information. The required parameter can be found in the proposal for the chemicals inventory (Chapter 5.3.1). When the activities are completed, an arrow leads to the control question D 1.1. If the answer is No, further efforts are required to complete the list. Yes leads to the next question D 1.2.

Digression on Strategy A to D:

The aim to bring more information on chemicals into BREF and to make information available on chemicals and used by all stakeholders using chemicals with regard to the IED turned out to be difficult. The expectation was to cover all substances used in an industrial sector. Therefore, four strategies were developed and for example the following were concluded:

- the use information provided by registrants in the ECHA database is for some branches very general;
- the composition of products and mixtures (with certain technical functions) often could not be identified;
- it is not satisfactory to limit BREFs only to SVHCs or other priority substances, otherwise many substances released into the environment from industry via wastewater (and other waste streams) would not be covered. Therefore, the interactive scheme for the identification of substances to be considered in BREF revision was developed.
- the case studies in the HAZBREF project have provided only fragmented information on the substances used in the specific industrial sector;

An important finding for the further development of BREFs is that inventories of the chemicals used in specific sectors should be compiled. This can be done specifically for installations and their processes, but also generically for technical and chemical functions and chemical groups on branch level. A very good example of this was dealt with in WP 2, starting from the textile processing sector. WP 2 demonstrated with the “Werschkun approach” (Strategy B) how chemical groups (based on technical functions) can be resolved into representative individual substances. With this approach, sector-specific substance groups can be compiled and substance data information in the ECHA database may be applied to chemical groups.

In WP 2 a two-step approach to identify relevant target substances that need to be reflected in BREFs was developed.

D 1.2 Collect data on relevant substance properties to perform risk evaluation

This decision and activity can primarily be carried out by installation operators but also by branch associations in order to support installation operators or by the TWG.

D 1.2: “Is the dataset on substance properties sufficient to perform an evaluation of the substance properties and risk assessment?” Again, which data is required can be found in the proposed inventory. If the question is answered with Yes the interactive scheme directs the user to the next question D 1.3. If the answer is No, the user is asked to carry out action A 1.2.

A 1.2: “Use appropriate databases or other sources to compile relevant data on substance properties”. In order to create a complete inventory of the substances used and to collect the latest data on the substance properties, the interactive scheme suggests various approaches. Current data on substance properties can be found in the ECHA database, the CPL inventory. Safety data sheets are also a helpful resource. However, the information in the safety data sheets is often not substance-specific, but relates to the product / mixture. In some cases, the data is not up to date as was shown during the project. In this case, the ECHA database should be searched for current data. In some cases industry reviews on substance properties exist. Again, when the activities are completed, an arrow leads to the control question D 1.2. If the answer is

No, further efforts are required to complete the information on substance properties. Yes leads to the next question D 1.3.

D 1.3 Check the regulatory status

If a full list of substances used is available, information on processes, where and how the substances are used, is complete and substance properties are updated, the regulatory status of the substances used should be determined. This decision and action can be conducted by all the mentioned stakeholders.

D 1.3 asks: “Is information on regulatory status for all substances recorded in your chemicals inventory?” Regulatory status means whether the substance is subject to certain use restrictions in national or European legislation and / or if regulation is expected. E.g. the substance might be regulated under the REACH Regulation (certain uses restricted, use is subject for authorisation, substance is on candidate list etc.), or identified as priority substance under Water Framework Directive (WFD), or BATs are derived under IED. If the answer is Yes the user is directed to D 1.4. No lead to the action A 1.3.

A 1.3: “Check the regulatory status of the substances used in an installation or branch. Choose one or more options suggested.” The interactive scheme suggests information sources where to find such information: Strategy C developed in WP 2 which provides an approach how to identify regulated substances relevant for a branch; The public activity coordination tool (PACT) on ECHA website where regulatory activities under REACH are summarized <https://echa.europa.eu/pact>; ECHA legislation finder EUCLEF to get an overview of regulations applicable for the substance <https://echa.europa.eu/information-on-chemicals/euclef> ; WP 3.2 report; SIN list consists of hazardous chemicals. It implies that these chemicals should be removed as soon as possible as they pose a threat to human health and the environment in the opinion of ChemSec. <https://chemsec.org/business-tool/sin-list/>. Again, when the activities are completed, an arrow leads to the control question D 1.3. If the answer is No, further efforts are required to complete information on regulatory status. Yes leads to the next question D 1.4.

D 1.4 Handle according to regulation

This decision and activity is primarily to be carried out by the installation operator.

D 1.4: “Have you checked if all legislative requirements for your substance are applied in your installation” Explanation to that question is available by clicking on the symbol. The user knows or found out with the last actions which requirements exist to use the substance safely and for which use there are specifications in various legislations. The user is now requested to check whether he is using all substances according to the specifications. Handle according to regulation means: a) with regard to REACH: you handle according to authorisation, handle according to restriction, you know the sunset date if the substance is subject of an authorisation requirement, applied for authorisation; b) with regard to the WFD: minimise or avoid releases, ...; c) according to national law ... If the answer is Yes the user is directed to D 1.5; No leads to the action A 1.4.

A 1.4: “Check if you handle in accordance to legislation and / or take respective measures to avoid releases to the environment. Check if regulation is expected and prepare for this regulation.” The user should record the outcome of the assessment in the chemicals inventory.

Again, when the activities are completed, an arrow leads to the control question D 1.4. If the answer is No, further efforts are required to handle substances in accordance to legislations. Yes leads to the next action A 1.5.

D 1.5 Substance enters the wastewater stream

This section starts with an action instead of a decision. Installation operators need to decide if the substance is released to waste water. The action to be carried out is A 1.5.

A 1.5: “Check if the substance enters the waste water stream.” To decide on that the user can run the standard release estimation tool used under REACH, SimpleTreat 4.0. To do so, he needs the substance properties compiled in the previous sections. In addition, expert judgement is necessary in the decision to consider process-integrated risk management measures to minimise releases into environment. If the installation operator is not able to assess whether the substance is released to the environment, the worst case assumption is that the substance enters the wastewater stream. For help the user can refer to ECHA Guidance R 16, ERC or to documents on SPERCs, or to the report of Appelgren et al., 2020 from the HAZBREF project. When the user of the interactive scheme has carried out the activity, the arrow leads to the decision question D 1.5.

D 1.5: “Do you expect that the substance is not released to the wastewater treatment?”. If the question is answered with Yes the substance is not relevant for the following process. The substance could nevertheless pose a risk to the environment if it can enter the environment via air or waste or is emitted during the service life. However, no process steps have been worked out for this, as this is outside of the scope of the HAZBREF project. The interactive scheme is structured in a way that the process steps can be supplemented at any time. If the question is answered with No, the user starts the next process: Block 2: two-step approach to identify relevant target substance. The process of Block 1 ends at this point.

Exposure Assessment under REACH: ERCs and SPERCs (according to R 12, ECHA, 2015)

Registrants need to assess environmental exposure for the substances they manufacture or import. The assessment of the environmental exposure has to cover the entire life cycle of the substance (manufacture, formulation, industrial / professional / consumer use, service life, waste stage). The REACH regulation provides Environmental Release Classes (ERC) for the environmental exposure assessment. According to R 12 REACH guidance (R 12 ECHA, 2015) the ERC categories are designed to label the characteristics of a use based on different aspects relevant from the environmental perspective:

1. The life cycle stage at which a use takes place. The life cycle stage is associated with specific type of emission / releases of the corresponding uses.
2. The technical fate (destination) of the substance resulting from the use. It indicates whether a substance is expected to become part of an article (either because it has a function in the article or because it remains in the article), is consumed (by reaction) on use and / or is expected to be released to soil, water, air or waste (e.g. they function as processing aid, surfactant or solvent in industrial use or product formulated, or substances are part of a functional fluid (hydraulic, lubricant)).
3. Indoor or outdoor use of a substance indicates whether direct releases to non-industrial soil or surface water may be relevant or may occur due to weathering conditions in case of articles.

4. Release-promoting conditions (such as abrasion during use, abrasive techniques, or intended releases)

As these ERCs are very generic, industry developed so-called *Special Environment Release Categories (SPERCs)* to improve the exposure assessment under REACH, i.e. making them more real. SPERCs are described in SPERCs-factsheets, which give information on the factors that influence the proportion of a substance emitted into the environment during its application in processes. These factors are, e.g. operational conditions like the amount used, duration or concentration of the substance that is used, the substance properties (e.g. volatility, solubility) or efficacy of risk mitigation measure such as on-site sewage treatment. As these operational conditions and risk mitigation measures are sector-specific, SPERCs are derived for several industrial sectors. SPERC factsheets can be found on the industrial sector association websites. Also, ECHA provides information on SPERCs. The European Chemical Industry Council CEFIC developed a standard factsheet document and guidance on the use of SPERCs in the environmental safety assessment for a substance. Information in SPERC factsheets may be a valuable source in the BREF process as they describe release conditions of certain potentially hazardous substances for available industrial application.

If it turns out that no SPERC is available for a substance used in the industrial plant, the potential to be released can also be estimated by experts using the fate and behaviour parameters mentioned in Chapter. The procedure for this is described in the interactive scheme and comprises the following steps in summary:

SPERCs:

https://echa.europa.eu/documents/10162/15669641/sperc_factsheet_guidance_en.pdf/4c94f0fb-07dd-4e9f-842a-3f21a63bd3fe

<https://cefic.org/app/uploads/2019/01/SPERCs-Specific-Environmental-Release-Classes-REACHImpl-ES-CSA-CSR.pdf>

ERCs: (use descriptor system)

https://echa.europa.eu/documents/10162/13632/information_requirements_r12_en.pdf/ea8fa5a6-6ba1-47f4-9e47-c7216e180197

2 The interactive scheme step-by-step: Block 2: identify relevant target substances

By using the interactive scheme, the plant operator, branch association or TWG is supported in the following steps in the Block 2:

B 2: The Block 2 begins with a yellow circle: Block 2 – Two step approach to identify (relevant) target substances. The user is asked to assess the substances used in an installation or a branch regarding the potential to be released and (eco)toxic properties and to identify where additional risk management measures are necessary.

The block consists of two steps: The aim of step 1 is to check if the substance has a potential to be released via WWTP into the environment by assessing the degradability and the mobility, and include expert judgement on the effect of end-of-pipe-measures on the release minimisation. The result of step 1 is the identification of target substances. The aim of the step 2 is the assessment of (eco)toxicological effects. The result of step 2 is the identification of relevant target substances

To decide on the decisions in block 2, the user is recommended to use the information from the chemicals inventory, which he has completed with the previous decisions and action in block 1.

From the yellow oval the user is directed to the first and very important decision D 2.1:

Decision on degradability

This decision is relevant for all users of the interactive scheme.

D 2.1: “Is the substance readily biodegradable?”

Besides the mechanical cleaning, the biological treatment stage is an essential part in treating waste water. Many substances can be degraded by microbial activity and this may be enhanced in WWT by adaptation of micro-organisms. Biodegradability is a key parameter in finding target substances. The more a substance is persistent, the higher is the possibility that the substance could be released from a WWTP and persist in the environment. Biodegradation is a complex process and may not be described by a single physico-chemical parameter. In the interactive scheme, the parameter ready biodegradability is used to decide whether the substance needs to be examined more closely or whether it is seen as non-target substance. The following parameters apply: Ready biodegradability (mineralisation of test item), test guideline OECD 301 a-f, OECD 310. A substance is readily biodegradable, if $\geq 60\%$ O₂ depletion or CO₂ development (pass level) is achieved an the 10-days-window is fulfilled. According to the test result, ready biodegradability is a yes/no decision and more a “classification” than a statement about the degradation behaviour. If the test criteria are narrowly missed, it is not possible to conclude on a “possible” or “inherent” degradability.

For the interactive scheme the WP 2 team decided that with regard to the assessment of the degradability only the test on ready biodegradability (OECD 301, OECD 310) is used as the decision criterion. If the substance is not readily biodegradable, that means the decision D 2.1 is decided with No, the substance will be examined in the further process of the interactive scheme. At the latest when the substance is identified as a relevant target substance at the end

of the block 2, further degradation test should be analysed. However, any other biodegradability classification e.g. inherently biodegradable, partly or non-biodegradable, degradation half-life dt_{50} (disappearance of 50% of the test item in 40 days in surface water) requires expert judgement for interpretation.

Yes directs the user to the decision-making process for readily biodegradable substances (D 2.2 to D 2.5).

No leads to the conclusion that the substance is not readily biodegradable and directs the user to the second important decision on mobility, D 2.6.

Decision making process for readily biodegradable substances

Within this decision-making process D 2.2 is relevant for all users including TWG, branch associations and installation operator. The decisions D 2.3 to D 2.5 mainly concerns the installation operator.

D 2.2: “The substance is not classified as toxic for the environment.”

In the IED, environmentally hazardous substances are also subject of BATs. This fact is also considered in the interactive scheme. Like the IED, the interactive scheme recommends that substances classified as hazardous for the environment be given special treatment. For this reason, this decision D 2.2 is introduced in the interactive scheme for readily biodegradable substances. The following parameter apply:

Short-term aquatic toxicity:

- H400: $EC/LC_{50} \leq 1$ mg/L aquatic acute toxic 1

Long-term aquatic toxicity:

- H410: aquatic chronic 1, $NOEC/EC_{10} \leq 0.1$ mg/L, substance not readily biodegradable
- H410: aquatic chronic 1, $NOEC/EC_{10} \leq 0.01$ mg/L, substance readily biodegradable

If the decision D 2.2 is No, the substance is regarded as readily biodegradable but toxic for the environment and further measures are required in case the substance is not degraded up to 100 % in the WWTP. In this case, TWG can derive BATs. The plant operator should take further measures to reduce emissions. A new process with decision-making questions would be desirable to identify suitable emission reduction measures or to design appropriate BATs. However, the development of this process was outside of the HAZBREF project.

If the decision is Yes, the user is directed to D 2.3.

D 2.3: “The amount of substance entering the WWTP does not lead to $PEC / PNEC > 1$ in environment?”

For this decision reference is to the approach proposed by ECHA: “Chemicals Management System – Methodology to prioritise chemicals for prevention or control of emissions” in the frame of the work on the textile BREF. Unfortunately this approach is not published by ECHA. However, this approach is based on the procedure proposed in ECHA guideline R 16 for exposure and risk assessment in accordance with REACH.

“The risk indicator takes into consideration the aggregated amount of the substance used on site (from different chemical products), the predicted no-effect-concentration (PNEC) for the water compartment, the biodegradability of the substance (assuming that the wastewater is treated in

a biological sewage treatment plant before final release to the environment), and a default dilution factor in the environment. ... The risk indicator expresses the relation of the substance amount potentially released and diluted in the environment [PEC] with the concentration of the substance causing adverse effects on the aquatic ecosystems (PNEC).”

If the decision is No, the substance is readily biodegradable, but the amount released leads to $PEC/PNEC > 1$. Operators have to derive mandatory appropriate measures for release minimization, as this is an obligation according to REACH.

If the decision is answered with Yes, the user is directed to D 2.4.

D 2.4: “The COD related to the amount of substance to be released into the environment is < 150 mg/L at WWTP effluent?”

The assessment of the COD is a decision based on practice in industrial plants. If the COD is > 150 mg/L at WWTP effluent further measures to reduce emissions are required.

If the decision needs to be decided with No the operator has to derive appropriate measures for release minimization (emission prevention and control measures).

If the decision is Yes, the user is directed to D 2.5.

D 2.5: “The substance is not found in waste water released to environment?”

This decision asks about existing monitoring data and can be seen as safety net. Operator can decide if additional measures for release minimization are necessary.

If the decision needs to be decided with No the substance is released to the environment although it is readily biodegradable. The installation operator should think about additional measures for release minimization (emission prevention and control measures).

If the decision is Yes the user is directed to the final conclusion of this decision-making process for readily biodegradable substances.

Conclusion: “The substance is readily biodegradable, not toxic for the environment, does not lead to $PEC/PNEC > 1$ in WWTP effluent, although the substance might be used in different products / mixtures and or processes, The COD is < 150 mg/L at WWTP effluent and the substance is not found in monitoring. **The substance seems not to be a target substance.**”

End: The process block 2 ends with the finding: “Elimination from waste water stream by degradation / biological treatment. Make sure that your WWTP has biological treatment and depletion rate is reached in the WWTP, e.g. by using adapted micro-organisms.”

If the decision on degradability, D 2.1 is decided with No, the substance is regarded as not readily biodegradable and the user is directed to the second important decision: mobility, D 2.6.

Decision on mobility

This decision is relevant for all users of the interactive scheme.

D 2.6: “Does the substance absorb to particles, suspended matter or sludge?”

In addition to the decision on biodegradability the decision on mobility is the second central substance property to decide on the potential to be released.

The substance is regarded as absorbtive (the substance is not mobile) if the following parameters are met:

- Adsorptivity $\log K_{oc} \leq 4$ (L/kg or dimensionless), test guideline OECD 106 or OECD 121 (HPLC-method) or calculation from $\log K_{ow}$. The organic carbon / water partition coefficient may only be measured or calculated for non-ionisable organic chemicals.
- Octanol-water distribution ratio $\log D_{ow} \leq 4$ (dimensionless, calculation from $\log K_{ow}$ and pKa). The octanol-water distribution ratio (D_{ow}) is a measure of K_{ow} that accounts for the pH dependency of an ionisable organic chemical, and is a measure of the distribution of dissociated and non-dissociated species in octanol and water as a function of pH (ECETOC Technical Report 123 (2014) – Environmental risk assessment of ionisable compounds (<https://www.ecetoc.org/publication/tr-123-environmental-risk-assessment-of-ionisable-compounds/>), section “Partition coefficient (K_{ow}) and distribution ratio (D_{ow})”)

If the substance has a $\log K_{oc} \leq 4$ or a $D_{ow} \leq 4$ the decision is to be decided with Yes. The user is then directed to the decision-making process on other concerns based on fate and behavior of substances (which are not readily biodegradable and not mobile). This decision-making process includes the decisions D 2.7 to D 2.9.

No forwards to D 2.10 which asks the user to investigate the influence of end-of-pipe measures on the emission of substances via WWTP to the environment.

Decision-making process on other concerns based on fate and behaviour

Within this decision-making process D 2.7 and D 2.8 are of relevance for all users. D 2.9 is in particular relevant for installation operator.

D 2.7: “The substance is not bioaccumulative?”

Not readily biodegradable substances can accumulate in plants and other organisms in the environment. It is therefore necessary to check whether the substance meets the criteria for bioaccumulation. These are the following (check table 1):

If the decision is No, the substance is bioaccumulative. In this case, the persistence and toxicity of the substance should be assessed. That means, a PBT assessment according to REACH is to be carried out. If the substance is not bioaccumulative, appropriate measures for release minimisation should be derived anyway. It is important to consider that the substance might be used in different products / mixtures or processes and the PEC / PNEC ratio need to be < 1 .

If the decision is Yes, the user is directed to decision D 2.8.

D 2.8: “Could a release of the substance be prevented by safe sludge processing?”

Substances can enter the environment via various pathways. Substances that absorb to particles, suspended matter or sludge can be emitted into the environment via sludge application. At this point in the interactive scheme, substances are considered not biodegradable. Emission into environment should therefore be avoided. For this reason, it must be checked whether release of the substance could be prevented by safe sludge processing. In case of TWG it should be checked whether safe sludge processing need to be prescribed in a BAT for the respective substance.

If the decision is NO, the first step is to check whether the substance is toxic. Suitable measures for safe handling must be derived. This must take into account that the substance might be used in different products / mixtures or processes which could lead to a PEC / PNEC ratio > 1 .

If the decision is Yes, the user is directed to D 2.9.

D 2.9: “The substance is not found in waste water released to environment?”

This decision is similar to decision D 2.5. However, in this case the decision is not just a safety net. Because, if the decision is No a not readily biodegradable substance is found in the effluent of the WWTP. An assessment of the toxicity and the PEC / PNEC ratio should be followed by considerations on further emission reduction. When calculating the PEC / PNEC ratio it must be considered that the substance might be used in different products / mixtures or processes. Provisions for emission reduction should also be considered in permitting process.

If the decision is Yes the user is directed to the final conclusion of this decision-making process on other concerns based on fate and behavior of substances.

Conclusion: “The substance is not readily biodegradable, absorbs to particle, suspended matter or sludge, but is not released via sludge to the environment, is not bioaccumulative, thus not a PBT-substance and the substance is not found in monitoring. **The substance seems not to be a target substance.**”

End: The process block 2 ends.

Decision on end-of-pipe measures

This decision is applicable for all user groups mentioned so far.

D 2.10: “Could a release of the substance with water be prevented by devices already installed?”

End-of-pipe measures contribute to the elimination of substances from wastewater. Whether the end-of-pipe-measures applied at the WWTP you release to, are suitable for the elimination of a not readily biodegradable and at the same time mobile substance, is examined at this point of the interactive scheme. From the multitude of possible processes in a WWTP the following measures are listed as examples. In the analyses it is irrelevant whether it is your own WWTP or a third-party facility.

Not exhaustive list:

- Does the substance form an emulsion? Could the emulsion be dissipated completely, e.g. by using a fat separator?
- Is the substance liquid and forms layers in waste water?
- Does the substance float due to density lower than water? Could the substance be removed from water surface by devices already installed?
- Could the substance be degassed from water, e.g. by changing temperature and/ or air pressure?
- Could the substance be precipitated or flocculated?
- Could the substance be removed from water with additional devices e.g. active charcoal filter?

If the substance can be eliminated from waste water stream with end-of-pipe measures installed (decision is Yes) the substance seems not to be a target substance. In this case the process block 2 ends with the following recommendations: “Elimination by end-of-pipe measures. Make sure

that the WWTP you release to has appropriate end-of-pipe measures. Make sure that PEC / PNEC is > 1.”

If the decision is No the user is directed to the following conclusion:

Conclusion: the substance is not readily biodegradable and mobile.

This conclusion leads to the following intermediate result:

Intermediate result: “The substance is a target substance for release to water, as it has the potential to be released to the environment.”

This group of substances has properties that give rise to concern besides the criteria for identification as “hazardous” e.g. according to CLP (which will be analysed in step 2 of block 2) and should be used with caution. Once released to the environment they can pose a risk to the environment or human health even without having any yet identified adverse effects on the environment or on human health via the environment.

Further measures are necessary:

- For operators: substitution, release minimisation up to prevention of emission, safe handling, check if substance belongs to substance group of concern, e.g. PFAS, check information on ECHA website for assessment of chemical universe;
- For branch associations: give advice to installation operators, conduct research for substitution, ...
- For TWG: derive BATs for BREFs, make sure that actual state of knowledge is reflected in BREFs at any time.

From this intermediate result the user is directed to the last decision D 2.10.

Decision on (eco)toxicological concern

This decision is applicable for all users.

D 2.11: “Does the substance not fulfil one of the parameters for toxicity or ecotoxicity?”

Target substances which fulfil one of the following parameters are relevant target substances for BREFs.

The following parameter apply:

Human health, according to CLP regulation:

- Carcinogenic cat. 1A or 1B,
- Germ cell mutagenic cat. 1A or 1B,
- Toxic for reproduction cat. 1 A or 1B or 2 (according to concept proposal PMT),
- Chronic toxicity (STOT RE) cat. 1 or 2,

Environment:

Short-term aquatic toxicity:

- according to ECHA Guidance R.11: EC/LC₅₀ < 0.1 mg/L screening T within PBT-assessment,
- according to CLP regulation: H400: EC/LC₅₀ ≤ 1 mg/L aquatic acute toxic 1

Long-term aquatic toxicity:

- according to ECHA guidance R.11: NOEC/EC₁₀ < 0.01 mg/L T-criterion within PBT criterion,
- according to CLP regulation: H410: aquatic chronic 1, NOEC/EC₁₀ ≤ 0.1 mg/L, substance not readily biodegradable; H410: aquatic chronic 1, NOEC/EC₁₀ ≤ 0.01 mg/L, substance readily biodegradable

If the decision is Yes, the substance does not fulfill one of the criteria for toxicity or ecotoxicity. However, this decision does not change the conclusion and result after decision D 2.10.

Conclusion: The substance is not readily biodegradable and is mobile. But the substance does not have (eco)toxicological properties of concern.

Final result 1: = intermediate result (see above)

If the decision is No, the substance is not readily biodegradable and in mobile and has (eco)toxicological properties of concern.

In this case the final result is the following:

Final result 2: The substance is a relevant target substance for release to water, as it has a potential to be released via WWTP to the environment and has the potential to cause a risk for the environment or human health via the environment.

Further measures are necessary for operators, branch associations, TWG (e.g. derive BAT)

End: The process block 2 ends.