**Template #32: Bioaccumulation: aquatic / sediment *(Version [9.3]-[July 2023])***

The following table gives a detailed description of the type of information prompted for by the data entry fields.

| **Line no.** | **Field name** | **Field type****Display type** | **Picklist****Freetext template** | **Help text** | **Remarks** **Guidance** **Cross-reference** |
| --- | --- | --- | --- | --- | --- |
|  | **Administrative data** | **Header 1** |  |  |  |
|  |  | ConfidentialityDisplay: Basic |  |  |  |
|  | Endpoint | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- bioaccumulation in aquatic species: fish- bioaccumulation in aquatic species: invertebrate- bioaccumulation in aquatic species: algae / cyanobacteria- bioaccumulation in aquatic species: aquatic plant- bioaccumulation in aquatic species, other- bioaccumulation in sediment species: invertebrate- bioaccumulation in sediment species, other | From the picklist select the relevant endpoint addressed by this study summary. In some cases there is only one endpoint title, which may be entered automatically depending on the software application.If multiple study types are covered by the same data entry form, the specific study type should be selected. If none matches, select the more generic endpoint description '<Generic endpoint>, other' (e.g. Skin irritation / corrosion, other) and give an explanation in the adjacent text field. The generic endpoint title reflects the title of the corresponding OECD Harmonised Template (OHT).Please note: For (Q)SAR studies, if an 'in silico' option does not exist, the generic endpoint title should be selected, normally with no need to fill in the adjacent text field, as '(Q)SAR' needs to be indicated in field 'Type of information' and the model should be described in field 'Justification of non-standard information' or 'Attached justification'. A specific endpoint title may be used, if addressed by the (Q)SAR information, i.e. the model behind has been validated by experimental data addressing this endpoint.Note: For the purpose of OHTs, an 'endpoint' is defined in the rather broad sense as an observable or measurable inherent property of a chemical substance which may be specified by the relevant regulatory framework as 'information requirement' (e.g. Boiling point, Sub-chronic toxicity: oral, Fish early-life stage toxicity). In a narrower sense, the term '(eco)toxicity endpoint' refers to an outcome or effect observed in a study. | **Guidance for data migration:**The relevant target phrase is selected as triggered by the value(s) of source fields 'Guideline', 'Test organisms (species)' and 'Route of exposure'. As a fallback the generic phrase 'bioaccumulation: aquatic / sediment' is selected.Note: The generic phrase is only used for migration, but otherwise deactivated in the picklist. For new entries a generic phrase is provided which consists of the OHT title followed by 'other', i.e. <OHT title>, other. |
|  | Type of information | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- experimental study- experimental study planned- experimental study planned (based on read-across)- (Q)SAR- calculation (if not (Q)SAR)- read-across based on grouping of substances (category approach)- read-across from supporting substance (structural analogue or surrogate)- read-across from similar mixture/product- mixture rules calculation- weight of evidence justification/conclusion- not specified- other: | Select the appropriate type of information, e.g. ' experimental study', ' experimental study planned' or, if alternatives to testing apply, '(Q)SAR', 'read-across ...'. In the case of calculated data, the value 'calculation (if not (Q)SAR)' should only be chosen if the study report does not clearly indicate whether it is based on '(Q)SAR'.If the information is taken from a handbook or review article, select the relevant item, e.g. ‘experimental study’, if this is provided in the information source. Otherwise select ‘not specified’. Please note: In field ‘Reference type’ the option ‘review article or handbook’ should be selected. In general, the option 'not specified' should be selected if the submitter lacks the knowledge of the type of information. The option 'other:' can be used if another than a pre-defined item applies.In the case of read-across, follow the instructions related to the relevant legislation, for instance as to whether the (robust) study summary should be entered in a separate data set defined for the read-across (source) substance and referenced in the target substance dataset.If 'experimental study planned' or 'experimental study planned (based on read-across)' is indicated (in some legislations also defined as 'testing proposal' or 'undertaking of intended submission'), the submitter should include as much information as possible on the planned study in order to support the evaluation of the proposal. Typically, this would include at least the test guideline, information on the test material, the species and the route of administration in the corresponding distinct fields, as appropriate.Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on whether specific fields should be completed and/or further details should be attached in field 'Attached background material'. |  |
|  | Adequacy of study | List (picklist)Display: Basic | **Picklist values:**- key study- supporting study- weight of evidence- disregarded due to major methodological deficiencies- other information | Indicate the adequacy of a (robust) study summary in terms of usefulness for hazard/risk assessment purposes depending on the relevant legislation.Note: This field is only applicable (or active) if neither 'waiving of standard information' nor 'experimental study planned' has been selected in field 'Type of information'.Explanation: - key study: In general, a key study is the study that has been identified as most suitable to describe an endpoint from the perspective of quality, completeness and representativity of data. - supporting study: Any other adequate study that is considered supportive for the key study or key studies. - weight of evidence: A record that contributes to a weight of evidence justification for the non-submission of a particular (adequate) study. The weight of evidence justification is normally endpoint-related, i.e. based on all available records included in the weight of evidence evaluation. A short reasoning for why a given record is used in this respect can be provided in field 'Detailed justification / remarks'. - disregarded due to major methodological deficiencies: study that demonstrates a higher concern than the key study/ies, but is not used as key study because of flaws in the methodology or documentation. This phrase should be selected for justifying why a potentially critical result has not been used for the hazard assessment. The lines of argumentation should be provided in field 'Rationale for reliability incl. deficiencies', accompanied by the appropriate reliability score.- other information: any other non-relevant information which does not need to be flagged specifically as 'disregarded due to major methodological deficiencies'.Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on how to use this field. | **Guidance for field condition:**Condition: Field active only if 'Type of information' is not 'experimental study planned' and not ‘experimental study planned (based on read-across)’ and field 'Data waiving' is not populated (except for migrated data) |
|  | Robust study summary | Check boxDisplay: Basic |  | Set this flag if relevant for the respective regulatory programme or if otherwise useful as filter for printing or exporting records flagged as 'Robust Study Summary' or in combination with 'Adequacy of study'. Explanation: The term 'Robust Study Summary' is actually used only to describe the technical content of a very detailed summary of an experimental study or of any other relevant information. It is a priori no synonym with the term 'Key study', although a key study should usually be submitted in the form of Robust Study Summary. However, a Robust Summary may also be useful for other adequate studies that are considered supportive of the key study or even for inadequate studies if they can be used for a weight-of-evidence analysis. Also for studies that are flawed, but indicate critical results, Robust Study Summaries highlighting the weaknesses of the studies need to be elaborated. Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on how to use this field. |  |
|  | Used for classification | Check boxDisplay: Basic |  | Set this flag if relevant for the respective regulatory programme or if otherwise useful as filter for printing or exporting records flagged as 'Used for classification'.Explanation: In some use cases it may be necessary to indicate those records that are used for the classification of that substance, e.g. according to UN GHS. If not relevant, disregard this field. Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on how to use this field. |  |
|  | Used for SDS | Check boxDisplay: Basic |  | Set this flag if relevant for the respective regulatory programme or if otherwise useful as filter for printing or exporting records flagged as 'SDS information'. Explanation: 'SDS' stands for Safety Data Sheet. In some use cases it may be necessary to indicate those records that are used for the compilation of SDS information. If not relevant, disregard this field. Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on how to use this field. |  |
|  | Study period: start date | DateDisplay: Basic |  | If applicable indicate the period during which the study was conducted, i.e. start and end date. Note: independent of the study period, the in-life period (i.e. the phase of a study following treatment in which the test system is alive/growing) may have to be specified for some toxicology endpoints. |  |
|  | End date | DateDisplay: Basic |  |  |  |
|  | Remark | Text (255 char.)Display: Basic |  |  |  |
|  | Reliability | List (picklist)Display: Basic | **Picklist values:**- 1 (reliable without restriction)- 2 (reliable with restrictions)- 3 (not reliable)- 4 (not assignable)- other: | Enter an appropriate reliability score, according to Klimisch et al. (1997):1 = reliable without restrictions: “studies or data [...] generated according to generally valid and/or internationally accepted testing guidelines (preferably performed according to GLP) or in which the test parameters documented are based on a specific (national) testing guideline [...] or in which all parameters described are closely related/comparable to a guideline method.”2 = reliable with restrictions: “studies or data [...] (mostly not performed according to GLP), in which the test parameters documented do not totally comply with the specific testing guideline, but are sufficient to accept the data or in which investigations are described which cannot be subsumed under a testing guideline, but which are nevertheless well documented and scientifically acceptable.”3 = not reliable: “studies or data [...] in which there were interferences between the measuring system and the test substance or in which organisms/test systems were used which are not relevant in relation to the exposure (e.g. non-physiological pathways of application) or which were carried out or generated according to a method which is not acceptable, the documentation of which is not sufficient for assessment and which is not convincing for an expert judgment.”4 = not assignable: “studies or data [...] which do not give sufficient experimental details and which are only listed in short abstracts or secondary literature (books, reviews, etc.).”The 'other:' option may be selected if a different scoring system is used. Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on how to use this field.Note: This field is only applicable (or active) if neither 'waiving of standard information' nor 'experimental study planned' has been selected in field 'Type of information'.Note: The term reliability defines the inherent quality of a test report or publication relating to preferably standardised methodology and the way the method and results are described. More detailed criteria can be selected in field 'Justification'. |  |
|  | Rationale for reliability incl. deficiencies | List sup. (picklist with remarks - 32,000 char.)Display: Basic | **Picklist values:**- guideline study - [Reliability 1]- comparable to guideline study - [Reliability 1]- test procedure in accordance with national standard methods - [Reliability 1]- test procedure in accordance with generally accepted scientific standards and described in sufficient detail - [Reliability 1]- guideline study without detailed documentation - [Reliability 2]- guideline study with acceptable restrictions - [Reliability 2]- comparable to guideline study with acceptable restrictions - [Reliability 2]- test procedure in accordance with national standard methods with acceptable restrictions - [Reliability 2]- study well documented, meets generally accepted scientific principles, acceptable for assessment - [Reliability 2]- accepted calculation method - [Reliability 2]- data from handbook or collection of data - [Reliability 2]- significant methodological deficiencies - [Reliability 3]- unsuitable test system - [Reliability 3]- abstract - [Reliability 4]- secondary literature - [Reliability 4]- documentation insufficient for assessment - [Reliability 4]- results derived from a valid (Q)SAR model and falling into its applicability domain, with adequate and reliable documentation / justification - [Reliability 1 or 2]- results derived from a valid (Q)SAR model and falling into its applicability domain, with limited documentation / justification - [Reliability 2, 3 or 4]- results derived from a valid (Q)SAR model, but not (completely) falling into its applicability domain, with adequate and reliable documentation / justification - [Reliability 2 or 3]- results derived from a (Q)SAR model, with limited documentation / justification, but validity of model and reliability of prediction considered adequate based on a generally acknowledged source - [Reliability 2 or 3]- results derived from a valid (Q)SAR model, but not (completely) falling into its applicability domain, and documentation / justification is limited - [Reliability 3 or 4]- results derived from a (Q)SAR model, with limited documentation / justification - [Reliability 4]- other: | Select an appropriate standard justification from the picklist, e.g. 'Comparable to guideline study with acceptable restrictions'. Additional explanations (e.g. deficiencies observed) can be entered in the related supplementary text field. Particularly if reliability scores 2 or 3 are assigned, indicate the concrete arguments for defending a study or relevant deficiencies.For QSAR results (i.e. 'Type of information' is '(Q)SAR') some pre-defined phrases are provided for indicating if the prediction results are considered reliable based on the scientifically validity of the (Q)SAR model used, its applicability to the query substance, and the adequacy of reporting. Please note: If (Q)SAR results are flagged as key study in field 'Adequacy of study', the relevance of the model used for the regulatory endpoint should be documented in the field where the (Q)SAR model is described, i.e. 'Justification for type of information', 'Attached justification' or 'Cross-reference'. | **Guidance for field condition:**Condition: Field active only if 'Type of information' is not 'experimental study planned' and not ‘experimental study planned (based on read-across)’.Condition 1: If 'Type of information' is not '(Q)SAR':- guideline study - [Reliability 1]- comparable to guideline study - [Reliability 1]- test procedure in accordance with national standard methods - [Reliability 1]- test procedure in accordance with generally accepted scientific standards and described in sufficient detail - [Reliability 1]- guideline study without detailed documentation - [Reliability 2]- guideline study with acceptable restrictions - [Reliability 2]- comparable to guideline study with acceptable restrictions - [Reliability 2]- test procedure in accordance with national standard methods with acceptable restrictions - [Reliability 2]- study well documented, meets generally accepted scientific principles, acceptable for assessment - [Reliability 2]- accepted calculation method - [Reliability 2]- data from handbook or collection of data - [Reliability 2]- significant methodological deficiencies - [Reliability 3]- unsuitable test system - [Reliability 3]- abstract - [Reliability 4]- secondary literature - [Reliability 4]- documentation insufficient for assessment - [Reliability 4]Condition 2: If 'Type of information' = '(Q)SAR':- results derived from a valid (Q)SAR model and falling into its applicability domain, with adequate and reliable documentation / justification - [Reliability 1 or 2]- results derived from a valid (Q)SAR model and falling into its applicability domain, with limited documentation / justification - [Reliability 2, 3 or 4]- results derived from a valid (Q)SAR model, but not (completely) falling into its applicability domain, with adequate and reliable documentation / justification - [Reliability 2 or 3]- results derived from a (Q)SAR model, with limited documentation / justification, but validity of model and reliability of prediction considered adequate based on a generally acknowledged source - [Reliability 2 or 3]- results derived from a valid (Q)SAR model, but not (completely) falling into its applicability domain, and documentation / justification is limited - [Reliability 3 or 4]- results derived from a (Q)SAR model, with limited documentation / justification - [Reliability 4]- other: |
|  | Data waiving | List (picklist)Display: Basic | **Picklist values:**- study technically not feasible- study scientifically not necessary / other information available- exposure considerations- study waived due to provisions of other regulation- other justification | If appropriate, indicate here that the study has been waived, i.e. not performed. Select the basis from the picklist (e.g. 'study technically not feasible' or 'other justification'). Include a more detailed justification in the field 'Justification for data waiving' and, as needed, in field 'Justification for type of information', 'Attached justification' and/or 'Cross-reference'. Please note: the option 'study scientifically not necessary / other information available' covers cases where it can be justified that performance of a specific study prescribed by the relevant legislation is scientifically not necessary because reliable information is provided in other part(s) of the submission document.The option 'study waived due to provisions of other regulation' can be used for indicating that another, overlapping regulation allows or requires the waiving of a specific information requirement. This should then be detailed in the justification fields.If waiving is based on several lines of argumentation (e.g. ‘exposure considerations’ and ‘study scientifically not necessary / other information available’), create separate records for each.Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on how to use data waivers. | **Guidance for field condition:**Condition: Deactivate this field if any of the following fields is populated: 'Type of information', 'Adequacy of study', 'Reliability', 'Rationale for reliability'. |
|  | Justification for data waiving | List multi. (multi-select list with remarks - 32,000 char.)Display: Basic | **Picklist values:**- the study does not need to be conducted because direct and indirect exposure of the aquatic compartment to the substance is unlikely - [exposure considerations]- the study does not need to be conducted because the substance has a low potential for bioaccumulation based on log Kow <=3, and the bioaccumulation properties of the substance are solely driven by lipophilicity - [study scientifically not necessary / other information available]- the study does not need to be conducted because the substance has a low potential for bioaccumulation based on log Kow <=3 and a low potential to cross biological membranes, and the bioaccumulation properties of the substance are solely driven by lipophilicity - [study scientifically not necessary / other information available]- the study does not need to be conducted because the substance has a low potential to cross biological membranes - [study scientifically not necessary / other information available]- other: | In addition to the more generic justification selected in the preceding field 'Data waiving', it is highly recommended to provide a detailed justification. To this end you can either select one or multiple specific standard phrase(s) if it/they give an appropriate rationale of the description given in the preceding field 'Data waiving' or 'other:' and enter free text. Additional specific explanations should be provided if the pre-defined phrase(s) do no sufficiently describe the justification.More details can be provided using the following fields:- Text field adjacent to this field 'Justification for data waiving' (available after selecting any picklist item in this field);- Field 'Justification for type of information';- Field 'Attached justification';- Cross-reference (for referencing / linking to a justification or information referred to in the justification which is stored in another record, e.g. a record describing physico-chemical properties information used to support a data waiver)Please note: The pre-defined phrases are not necessarily exhaustive and may not always apply. Consult the guidance documents and waiving options in the relevant regulatory frameworks. If no suitable phrase is available from the picklist, enter a free text justification using the 'other:' option. | **Guidance for field condition:**Condition: Deactivate this field if any of the following fields is populated: 'Type of information', 'Adequacy of study', 'Reliability', 'Rationale for reliability'. |
|  | Justification for type of information | Text templateDisplay: Basic | **Freetext template:Option 1 Type 'Waiving of standard information'**JUSTIFICATION FOR DATA WAIVING[Specific explanation in addition to field 'Justification for data waiving']**Option 2 Type 'Experimental study planned / Testing proposal on vertebrate animals'**TESTING PROPOSAL ON VERTEBRATE ANIMALS[Please provide information for all of the points below. The information should be specific to the endpoint for which testing is proposed. Note that for testing proposals addressing testing on vertebrate animals under the REACH Regulation this document will be published on the ECHA website along with the third party consultation on the testing proposal(s).]NON-CONFIDENTIAL NAME OF SUBSTANCE:- Name of the substance on which testing is proposed to be carried out- Name of the substance for which the testing proposal will be used [if different from tested substance]CONSIDERATIONS THAT THE GENERAL ADAPTATION POSSIBILITIES OF ANNEX XI OF THE REACH REGULATION ARE NOT ADEQUATE TO GENERATE THE NECESSARY INFORMATION [please address all points below]:- Available GLP studies- Available non-GLP studies- Historical human/control data- (Q)SAR- In vitro methods- Weight of evidence- Grouping and read-across- Substance-tailored exposure driven testing [if applicable]- Approaches in addition to above [if applicable]- Other reasons [if applicable]CONSIDERATIONS THAT THE SPECIFIC ADAPTATION POSSIBILITIES OF ANNEXES VI TO X (AND COLUMN 2 THEREOF) OF THE REACH REGULATION ARE NOT ADEQUATE TO GENERATE THE NECESSARY INFORMATION:- [free text]FURTHER INFORMATION ON TESTING PROPOSAL IN ADDITION TO INFORMATION PROVIDED IN THE MATERIALS AND METHODS SECTION:- Details on study design / methodology proposed [if relevant]**Option 3 Type 'QSAR prediction'**1. SOFTWARE2. MODEL (incl. version number)3. SMILES OR OTHER IDENTIFIERS USED AS INPUT FOR THE MODEL4. SCIENTIFIC VALIDITY OF THE (Q)SAR MODEL[[Explain how the model fulfils the OECD principles for (Q)SAR model validation. Consider attaching the QMRF and/or QPRF or providing a link]- Defined endpoint:- Unambiguous algorithm:- Defined domain of applicability:- Appropriate measures of goodness-of-fit and robustness and predictivity:- Mechanistic interpretation:5. APPLICABILITY DOMAIN[Explain how the substance falls within the applicability domain of the model]- Descriptor domain:- Structural domain:- Mechanistic domain:- Similarity with analogues in the training set:- Other considerations (as appropriate):6. ADEQUACY OF THE RESULT[Explain how the prediction fits the purpose of classification and labelling and/or risk assessment]**Option 4 Type 'Read-across (analogue)'**REPORTING FORMAT FOR THE ANALOGUE APPROACH[Please provide information for all of the points below. Indicate if further information is included as attachment to the same record, or elsewhere in the dataset (insert links in 'Cross-reference' table)]1. HYPOTHESIS FOR THE ANALOGUE APPROACH[Describe why the read-across can be performed (e.g. common functional group(s), common precursor(s)/breakdown product(s) or common mechanism(s) of action]2. SOURCE AND TARGET CHEMICAL(S) (INCLUDING INFORMATION ON PURITY AND IMPURITIES)[Provide here, if relevant, additional information to that included in the Test material section of the source and target records]3. ANALOGUE APPROACH JUSTIFICATION[Summarise here based on available experimental data how these results verify that the read-across is justified]4. DATA MATRIX**Option 5 Type 'Read-across (category)'**REPORTING FORMAT FOR THE CATEGORY APPROACH[Please provide information for all of the points below addressing endpoint-specific elements that were not already covered by the overall category approach justification made available at the category level. Indicate if further information is included as attachment to the same record, or elsewhere in the dataset (insert links in 'Cross-reference' table)]1. HYPOTHESIS FOR THE CATEGORY APPROACH (ENDPOINT LEVEL)[Describe why the read-across can be performed]2. CATEGORY APPROACH JUSTIFICATION (ENDPOINT LEVEL[Summarise here based on available experimental data how these results verify that the read-across is justified]**Option 6 Type 'Weight of Evidence justification'**JUSTIFICATION FOR WEIGHT OF EVIDENCE- Relevance (including coverage) and reliability of each source of information compared with the study normally required for the information requirement.- Weighing of the sources of information (including overall coverage) to reach an overall conclusion for the information requirement.- Assessment of the uncertainty in the conclusion compared with the study normally required for the information requirement. | This field can be used for entering free text. As appropriate, one of the freetext templates can be selected (e.g. Justification for read-across (analogue)) to use pre-defined headers and bulleted elements. Delete/add elements as appropriate.Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on what should be taken into account when providing justifications or whether specific reporting formats should be used.Explanations:Option 1: Type 'Waiving of standard information':This field should be used for entering any further lines of argumentation, if necessary, in addition to those provided in the field 'Justification for data waiving'.Option 2: Type 'Experimental study planned / Testing proposal':Further details can be entered here on the study design / methodology proposed in addition to details given in the distinct fields on test guideline, test material, species, route of administration and other relevant fields.Option 3: Type 'QSAR prediction':For describing a (Q)SAR model it is recommended to provide the QMRF as attachment instead of using the free text template.The QSAR Model Reporting Format (QMRF) is a harmonised template for summarising and reporting key information on QSAR models, including the results of any validation studies. The information is structured according to the OECD validation principles and can be compiled using the QMRF editor application.The JRC QSAR Model Database is intended to help to identify valid (Q)SARs (e.g. for the purpose of REACH). It provides information on the validity of QSAR models and can be browsed for published QMRFs.Based on this freetext template details on the QSAR model used can be given, in addition to the information provided in field 'Principles of method if other than guideline'.Please note: Any information that can be re-used for several study summaries can be entered once and then assigned to the relevant studies using either the 'Attached justification' or 'Cross-reference' feature.Option 4: Type 'Read-across (analogue)' and Option 5: Type 'Read-across (category)'This freetext template can be used and modified as appropriate for providing a justification for read-across, particularly if it is endpoint-specific.Please note: Any information that can be re-used for several study summaries can be entered once and then assigned to the relevant studies using either the 'Attached justification' or 'Cross-reference' feature. |  |
|  | **Attached justification** | **Block of fields (repeatable) Start** |  | The Attached justification feature can be used in case the justification is best provided in form of attached document(s).Copy this block of fields for attaching more than one file.Refer to the relevant legislation-specific guidance document as to the recommended use of the Attached justification feature. |  |
|  | Attached justification | Attachment (single)Display: Basic |  | Upload file by clicking the upload icon. |  |
|  | Reason / purpose | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- data waiving: supporting information- exposure-related information- read-across: supporting information- (Q)SAR model reporting (QMRF)- (Q)SAR prediction reporting (QPRF)- (Q)SAR model and prediction reporting (QMRF/QPRF)- (Q)SAR: supporting information- weight of evidence: supporting information- justification, other: | Indicate the reason for / purpose of the attached document. Select the relevant item from the picklist or, if none applies, select 'justification, other:' and specify. |  |
|  | **Attached justification** | **Block of fields (repeatable) End** |  |  |  |
|  | **Cross-reference** | **Block of fields (repeatable) Start** |  | The cross-reference feature can be used to refer to related information that is provided in another record of the dataset. This can be done either by entering just free text in the 'Remarks' field or by creating a link to the relevant record. The field 'Reason / purpose' allows for selecting a standard reason from the picklist and optionally to add free text explanation in the related supplementary text field.Refer to the relevant legislation-specific guidance document as to the recommended use of cross-references. |  |
|  | Reason / purpose for cross-reference | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- adverse outcome pathway (AOP)- assessment report- data waiving: supporting information- defined approach- exposure-related information- method used in study- read-across source- (Q)SAR model reporting (QMRF)- read-across: supporting information- reference to other assay used for intermediate effect derivation- reference to other study- reference to same study- weight of evidence source- other: | Select the appropriate reason of the cross-reference, i.e.- adverse outcome pathway (AOP) (in case the information is related to a key event that is part of an AOP). Consult the AOP wiki at: https://aopwiki.org) and provide the reference in the remarks field- assessment report (for referring to a record that contains an assessment report as attachment)- data waiving: supporting information (for referring to a record containing relevant endpoint information that is used to justify a data waiver)- defined approach for combining with results from another methods (in vitro, in chimico, in silico) - exposure-related information (for referring to a record containing exposure-related information that is used for instance to justify a data waiver)- read-across source (for linking to another study summary used for read-across. This can be useful in cases where results are derived from one or several read-across sources and recorded in a separate (target) study summary.)- read-across supporting information (for linking to another record which contains read-across justification that applies also for the current study summary)- (Q)SAR model reporting (QMRF) (for referring to a record containing the relevant model description. Note: The (Q)SAR prediction should be reported specifically for each endpoint in the field 'Justification for type of information'.)- reference to other assay used for intermediate effect derivation (for optional indication in a study summarising 'intermediate effects' if reference is made to the outcome of another assay)- reference to same study (e.g. if different species were tested and the results recorded in different records), - reference to other study (e.g. if another study is considered relevant in the interpretation of the test results), - other: (to be specified). |  |
|  | Related information | Link to endpoint (single)Display: Basic |  | As appropriate, select the record containing the related information, thus creating a link. | **Cross-reference:**AllSummariesAndRecords |
|  | Remarks | Text (32,768 char.)Display: Basic |  | This field can be used for including any remarks. |  |
|  | **Cross-reference** | **Block of fields (repeatable) End** |  |  |  |
|  | **Data source** | **Header 1** |  |  |  |
|  | Reference | Link to lit. reference (multiple)Display: Basic |  | Indicate the bibliographic reference of the study report or publication the study summary is based on. Provide general information such as Title, Author, Year, Bibliographic source, Testing Facility, Report Number, Study number, Report date etc., as requested in the core template for literature search (https://www.oecd.org/ehs/templates/Generic%20elements%20for%20all%20OHTs.zip). Always enter the primary reference in the first block of fields or sort it to the first position, if there are more than one reference to be cited. Copy this block of fields for specifying any other references related to this record (e.g. report of a preliminary study or other documentation). If results of a study report have been published, indicate the full citation of that publication(s) in addition to the reference of the original study. |  |
|  | Data access | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- data submitter is data owner- data submitter has Letter of Access- data no longer protected- data published- data submitter has permission to refer- not applicable- other: | Select appropriate indication for data access. Enter 'Not applicable' if the summary consists of information that is commonly accessible such as guidance on safe use.Select 'data submitter has permission to refer' if the information requirement can be covered based on a permission to refer to old data as issued by the relevant regulatory agency. In addition, provide, in the adjacent free-text field, the statement according to instructions you received from the relevant regulatory authority together with the permission to refer. |  |
|  | Data protection claimed | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- yes- yes, but willing to share- yes, but not willing to share | Indicate as appropriate. Note: 'yes' should be selected only if 'Data submitter is data owner' or 'Data submitter has Letter of Access'. Options 'yes, but willing to share' or 'yes, but not willing to share' may be relevant for specific regulatory programmes where the submitter is requested to indicate whether he is willing to share studies conducted (e.g. with vertebrates).In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. 'for justification see attached document X') |  |
|  | **Materials and methods** | **Header 1** |  |  |  |
|  | **Test guideline** | **Block of fields (repeatable) Start** |  | Indicate according to which test guideline the study was conducted. If no test guideline was explicitly followed, but the methodology used is equivalent or similar to a specific guideline, you can indicate so in the 'Qualifier' subfield preceding the field 'Guideline'.Copy this block of fields for specifying more than one guideline (e.g. US EPA in addition to OECD guideline). |  |
|  | Qualifier | List (picklist)Display: Basic | **Picklist values:**- according to guideline- equivalent or similar to guideline- no guideline followed- no guideline available- no guideline required | Select appropriate qualifier, i.e.- 'according to guideline' (if a given test guideline was followed);- 'equivalent or similar to guideline' (if no test guideline was explicitly followed, but the methodology is equivalent or similar to a specific guideline);- 'no guideline followed' (if none of above qualifiers apply. If so, fill in field 'Principles of method if other than guideline');- 'no guideline available' (if so, fill in field 'Principles of method if other than guideline').- 'no guideline required' (if so, fill in field 'Principles of method if other than guideline'). |  |
|  | Guideline | List (picklist)Display: Basic | **Picklist values:**- OECD Guideline 305 (Bioaccumulation in Fish: Aqueous and Dietary Exposure) -I: Aqueous Exposure Bioconcentration Fish Test- OECD Guideline 305 (Bioaccumulation in Fish: Aqueous and Dietary Exposure) -II: Minimised Aqueous Exposure Fish Test- OECD Guideline 305 (Bioaccumulation in Fish: Aqueous and Dietary Exposure) -III: Dietary Exposure Bioaccumulation Fish Test- OECD Guideline 305 (Bioconcentration: Flow-through Fish Test) - [before 2 Oct 2012]- OECD Guideline 305 A (Bioaccumulation: Sequential Static Fish Test) - [before 14 June 1996]- OECD Guideline 305 B (Bioaccumulation: Semi-static Fish Test)- OECD Guideline 305 C (Bioaccumulation: Test for the Degree of Bioconcentration in Fish) - [before 14 June 1996]- OECD Guideline 305 D (Bioaccumulation: Static Fish Test) - [before 14 June 1996]- OECD Guideline 305 E (Bioaccumulation: Flow-through Fish Test) - [before 14 June 1996]- OECD Guideline 315 (Bioaccumulation in Sediment-dwelling Benthic Oligochaetes)- EU Method C.13 (Bioconcentration: Flow-through fish test)- EPA OPP 165-4 (Laboratory Studies of Pesticide Accumulation in Fish)- EPA OPP 72-6 (Aquatic Organism Accumulation Tests)- EPA OPPTS 835.4100 (Aerobic Soil Metabolism)- EPA OPPTS 835.4200 (Anaerobic Soil Metabolism)- EPA OPPTS 850.1710 (Oyster Bioconcentration Test)- EPA OPPTS 850.1730 (Fish Bioconcentration Test)- EPA OPPTS 850.1850 (Aquatic Food Chain Transfer)- EPA OTS 797.1520 (Fish Bioconcentration Test-Rainbow Trout)- EPA OTS 797.1830 (Oyster Bioconcentration Test)- EPA 600/R-94/024 (Methods for measuring the toxicity and bioaccumulation of sediment-associated contaminants with freshwater invertebrates)- ASTM E1688 (Standard guide for determination of bioaccumulation of sediment-associated contaminants by benthic invertebrates)- other: | Select the applicable test guideline, e.g. 'OECD Guideline xxx'. If the test guideline used is not listed, choose 'other:' and specify the test guideline in the related text field. Information on the version and date of the guideline used and/or any other specifics can be entered in the next field 'Version / remarks'.If no test guideline can be specified, this should be indicated in the preceding field 'Qualifier'. The method used should then be shortly described in the field 'Principles of method if other than guideline', while details can be given in other distinct fields.Please note: Test guidelines used for the validation of (Q)SAR models should be reported in the description of the relevant model in field 'Justification for type of information' or 'Attached justification'. | **Guidance for field condition:**Condition: Field active only if 'Qualifier' is not 'no guideline ...' |
|  | Version / remarks | Text (2,000 char.)Display: Basic |  | In this text field, you can enter any remarks as applicable, particularly:- To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline);- To indicate if the study was performed prior to the adoption of the test guideline specified;- To indicate if the methodology used was based on an extension of the test guideline specified;- To indicate what protocol was followed for methods that allow the optional determination of more than one parameter if this cannot be indicated in a distinct field of the Materials and methods section. | **Guidance for field condition:**Condition: Field active only if 'Qualifier' is not 'no guideline ...'**Guidance for data migration:**Version information (e.g. the year in a phrase) has been removed from phrase(s) of field 'Guideline'. This information is now added in field 'Version / remarks' preceding any supplementary remarks text migrated also from field 'Guideline'.Affected phrase(s) for this OHT: - 'ASTM E1688-95...' changed to 'ASTM E1688...'; default text in field 'Version / remarks': 'version: 95. Remark: supplementary remarks text' |
|  | Deviations | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- yes- no- not applicable- not specified | In case a test guideline or other standardised method was used, indicate if there are any deviations. Briefly state relevant deviations in the supplementary remarks field (e.g. 'other test system used', 'different exposure duration'); details should be described in the respective fields of the section MATERIALS AND METHODS. | **Guidance for field condition:**Condition: Field active only if 'Qualifier' is not 'no guideline ...' |
|  | **Test guideline** | **Block of fields (repeatable) End** |  |  |  |
|  | Principles of method if other than guideline | Text templateDisplay: Basic | **Freetext template:Option 1 Method of non-guideline study**- Principle of test:- Short description of test conditions:- Parameters analysed / observed:**Option 2 (Q)SAR**- Software tool(s) used including version:- Model(s) used:- Model description: see field 'Justification for non-standard information', 'Attached justification' and/or 'Cross-reference'- Justification of QSAR prediction: see field 'Justification for type of information', 'Attached justification' and/or 'Cross-reference' | If no guideline was followed, include a description of the principles of the test protocol or estimated method used in the study. As appropriate use either of the pre-defined freetext template options for 'Method of non-guideline study' or '(Q)SAR'. Delete / add elements and edit text set in square brackets [...] as appropriate.For a non-guideline experimental study a high-level freetext template can be used for summarising the principle of test, test conditions and parameters analysed / observed. If the freetext template for (Q)SAR is selected, indicate the QSAR model(s) or platform including version and the software tool(s) used. Detailed justification of the model and prediction should be provided in field(s) 'Justification for type of information', 'Attached justification' and/or 'Cross-reference' as appropriate.Details should be entered in appropriate distinct fields of section MATERIALS AND METHODS if available. Also provide a justification for using this method if appropriate. |  |
|  | GLP compliance | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- yes (incl. QA statement)- yes- no- not specified | Indicate whether the study was conducted following Good Laboratory Practice or not. In case 'yes’ is selected, a Quality Assurance (QA) statement must be provided with the report. You can give an explanation in the supplementary remarks field, e.g. for explaining why GLP was not complied with or for specifying which (national) GLP was followed. |  |
|  | **Test material** | **Header 2** |  |  |  |
|  | Test material information | Link to entity (single)Display: Basic |  | Select the appropriate Test Material Information (TMI) record. If not available in the repository, create a new one. You may also copy (clone) an existing TMI record, edit it and store it as new TMI.To change the link to an existing TMI, click the Delete button, then the Link button and proceed as described above.Depending on the purpose of the reporting or data submission, the information that must be provided may change. As a minimum, the chemical name, identifier and/or CAS number and molecular weight must be provided. | **Cross-reference:**TEST\_MATERIAL\_INFORMATION |
|  | Additional test material information | Link to entity (multiple)Display: Basic |  | Select additional Test material information record if relevant. For example, in longer terms studies more than one batch of test material can be needed or there may be differences between the labelled and unlabelled test materials. | **Cross-reference:**TEST\_MATERIAL\_INFORMATION |
|  | Specific details on test material used for the study | Text templateDisplay: Basic | **Freetext template:**SOURCE OF TEST MATERIAL- Source (i.e. manufacturer or supplier) and lot/batch number of test material:- Purity, including information on contaminants, isomers, etc.:RADIOLABELLING INFORMATION (if applicable)- Radiochemical purity:- Specific activity:- Locations of the label:- Expiration date of radiochemical substance:STABILITY AND STORAGE CONDITIONS OF TEST MATERIAL- Storage condition of test material:- Stability and homogeneity of the test material in the vehicle/solvent under test conditions (e.g. in the exposure medium) and during storage:- Stability in the medium, i.e. sensitivity of the test material to hydrolysis and/or photolysis:- Solubility and stability of the test material in the solvent/vehicle and the exposure medium:- Reactivity of the test material with the incubation material used (e.g. plastic ware):TREATMENT OF TEST MATERIAL PRIOR TO TESTING- Treatment of test material prior to testing (e.g. warming, grinding):- Preliminary purification step (if any):- Final concentration of a dissolved solid, stock liquid or gel:- Final preparation of a solid (e.g. stock crystals ground to fine powder using a mortar and pestle):FORM AS APPLIED IN THE TEST (if different from that of starting material)- Specify the relevant form characteristics if different from those in the starting material, such as state of aggregation, shape of particles or particle size distribution:INFORMATION ON NANOMATERIALS- Chemical Composition:- Density:- Particle size & distribution:- Specific surface area:- Isoelectric point:- Dissolution (rate):TYPE OF BIOCIDE/PESTICIDE FORMULATION (if applicable)- Description of the formulation, e.g. formulated product for foliar application; formulated product soil application; solution in organic solvent for soil application; formulated product seed treatment; solution in organic solvent seed treatment:OTHER SPECIFICS- Other relevant information needed for characterising the tested material, e.g. if radiolabelled, adjustment of pH, osmolality and precipitate in the culture medium to which the test chemical is added: | Use this field for reporting specific details on the test material as used for the study if they differ from the starting material specified under 'Test material information'. This can include information on the pre-defined items, but not all or additional ones may be relevant.Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) thereof.If applicable, relevant available information on the following items should be given:SOURCE OF TEST MATERIAL- Source and lot/batch No. of test material- Expiration date of the lot/batch- Purity test date: provide if availableRADIOLABELLING INFORMATION- Radiochemical purity- Specific activity- Locations of the label- Expiration date of radiochemical substanceSTABILITY AND STORAGE CONDITIONS OF TEST MATERIAL- Storage condition of test material- Stability under test conditions- Solubility and stability of the test substance in the solvent/vehicle- Reactivity of the test substance with the solvent/vehicle or the cell culture mediumTREATMENT OF TEST MATERIAL PRIOR TO TESTING- Treatment of test material prior to testing (e.g. warming, grinding)- Preliminary purification step- Final dilution of a soluble solid, stock liquid, or gel (e.g., neat liquid, stock diluted liquid, or dissolved solid) to final concentration and the solvent(s) used- Final preparation of a solid (e.g. stock crystals ground to fine powder using a mortar and pestle)FORM AS APPLIED IN THE TEST (if different from that of starting material)Specify the relevant form characteristics if different from those in the starting material, such as state of aggregation, shape of particles or particle size distribution.FORMULATED PRODUCT (for biocides/pesticides)Description of the formulation, e.g. formulated product for foliar application; formulated product soil application; solution in organic solvent for soil application: formulated product seed treatment; solution in organic solvent seed treatment.OTHER SPECIFICSProvide any other relevant information needed for characterising the tested material. |  |
|  | Specific details on test material used for the study (confidential) | Text templateDisplay: Basic (Confidential) | **Freetext template:**SOURCE OF TEST MATERIAL- Source (i.e. manufacturer or supplier) and lot/batch number of test material:- Purity, including information on contaminants, isomers, etc.:RADIOLABELLING INFORMATION (if applicable)- Radiochemical purity:- Specific activity:- Locations of the label:- Expiration date of radiochemical substance:STABILITY AND STORAGE CONDITIONS OF TEST MATERIAL- Storage condition of test material:- Stability and homogeneity of the test material in the vehicle/solvent under test conditions (e.g. in the exposure medium) and during storage:- Stability in the medium, i.e. sensitivity of the test material to hydrolysis and/or photolysis:- Solubility and stability of the test material in the solvent/vehicle and the exposure medium:- Reactivity of the test material with the incubation material used (e.g. plastic ware):TREATMENT OF TEST MATERIAL PRIOR TO TESTING- Treatment of test material prior to testing (e.g. warming, grinding):- Preliminary purification step (if any):- Final concentration of a dissolved solid, stock liquid or gel:- Final preparation of a solid (e.g. stock crystals ground to fine powder using a mortar and pestle):FORM AS APPLIED IN THE TEST (if different from that of starting material)- Specify the relevant form characteristics if different from those in the starting material, such as state of aggregation, shape of particles or particle size distribution:INFORMATION ON NANOMATERIALS- Chemical Composition:- Density:- Particle size & distribution:- Specific surface area:- Isoelectric point:- Dissolution (rate):TYPE OF BIOCIDE/PESTICIDE FORMULATION (if applicable)- Description of the formulation, e.g. formulated product for foliar application; formulated product soil application; solution in organic solvent for soil application; formulated product seed treatment; solution in organic solvent seed treatment:OTHER SPECIFICS- Other relevant information needed for characterising the tested material, e.g. if radiolabelled, adjustment of pH, osmolality and precipitate in the culture medium to which the test chemical is added: | Use this field for reporting specific details on the test material as used for the study if they differ from the starting material specified under 'Test material information'. This can include information on the pre-defined items, but not all or additional ones may be relevant.Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) thereof.If applicable, relevant available information on the following items should be given:SOURCE OF TEST MATERIAL- Source and lot/batch No. of test material- Expiration date of the lot/batch- Purity test date: provide if availableRADIOLABELLING INFORMATION- Radiochemical purity- Specific activity- Locations of the label- Expiration date of radiochemical substanceSTABILITY AND STORAGE CONDITIONS OF TEST MATERIAL- Storage condition of test material- Stability under test conditions- Solubility and stability of the test substance in the solvent/vehicle- Reactivity of the test substance with the solvent/vehicle or the cell culture mediumTREATMENT OF TEST MATERIAL PRIOR TO TESTING- Treatment of test material prior to testing (e.g. warming, grinding)- Preliminary purification step- Final dilution of a soluble solid, stock liquid, or gel (e.g., neat liquid, stock diluted liquid, or dissolved solid) to final concentration and the solvent(s) used- Final preparation of a solid (e.g. stock crystals ground to fine powder using a mortar and pestle)FORM AS APPLIED IN THE TEST (if different from that of starting material)Specify the relevant form characteristics if different from those in the starting material, such as state of aggregation, shape of particles or particle size distribution.FORMULATED PRODUCT (for biocides/pesticides)Description of the formulation, e.g. formulated product for foliar application; formulated product soil application; solution in organic solvent for soil application: formulated product seed treatment; solution in organic solvent seed treatment.OTHER SPECIFICSProvide any other relevant information needed for characterising the tested material. |  |
|  | Radiolabelling | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- yes- no- not specified | Indicate if labelled or non-labelled test material was used. Details on labelled material to be described in field 'Details on test material'. |  |
|  | **Sampling and analysis** | **Header 2** |  |  |  |
|  | Details on sampling | Text templateDisplay: Detailed | **Freetext template:**- Sampling intervals/frequency for test organisms: - Sampling intervals/frequency for test medium samples: - Sample storage conditions before analysis:  - Details on sampling and analysis of test organisms and test media samples (e.g. sample preparation, analytical methods): | Enter details on sampling. Use freetext template as appropriate and delete/add elements as appropriate. For sediment study, distinguish between sampling of sediment, pore water, and overlying water. |  |
|  | Details on analytical methods | Text templateDisplay: Detailed | **Freetext template:**DETAILS ON PRETREATMENT - Centrifugation:  - Filtration:  - Digestion (acid used, method: e.g. micro-oven):  - Extraction (solvent used, method: e.g. solid/liquid by soxhlet or ASE):  - Total 14C measurement:  - Clean up method: e.g. chemical used for chemistry method (Cu, Hg, ...) or phase and solvent used for SPE method:  - Derivatisation method if used:  - Concentration (method):   IDENTIFICATION AND QUANTIFICATION OF TEST SUBSTANCE/PRODUCT  - Separation method (e.g. HPLC, GC):  - Conditions (column, mobile phase, etc.):  - Detection method (e.g. ECD, UV, MS, ICP-AES, ICP-MS):  - Detection limits (LOD, LOQ) (indicate method of determination/calculation):  - Reproducibility in % (indicate method of evaluation; should be given for stated concentration levels):  - Linearity range:  - Internal or external calibration:  - Extraction recovery (indicate if results are corrected or not for recoveries):  - Method of confirmation of identity of measured compound: | Enter any details on the analytical methods used. Use freetext template and delete/add elements as appropriate. Specify treatment of fish and water samples, including details of preparation, storage, extraction and analytical procedures (and precision) for the test substance and lipid content (if measured).Copy any subheading(s) for the different matrices as appropriate. |  |
|  | **Test solutions** | **Header 2** |  |  |  |
|  | Vehicle | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- yes- no- not specified | Indicate whether vehicle was used to emulsify or mix the experimental test material to enhance its solubility, or prior to spiking food for the OECD 305 III: dietary bioaccumulation in fish study. If yes, specify in field 'Details on test solutions'. |  |
|  | Details on preparation of test solutions, spiked fish food or sediment | Text templateDisplay: Detailed | **Freetext template:Option 1 Type "Aquatic"**PREPARATION AND APPLICATION OF TEST SOLUTION (especially for difficult test substances) - Method:  - Controls:  - Chemical name of vehicle (organic solvent, emulsifier or dispersant):  - Concentration of vehicle in test medium (stock solution and final test solution(s) at different concentrations and in control(s)):  - Evidence of undissolved material (e.g. precipitate, surface film, etc): PREPARATION OF SPIKED FISH FOOD- Details on fish food (source, fat content as supplied, etc):- Details of spiking (e.g. i) liquid test material (neat); ii) with a vehicle (corn or fish oil); or iii) using an organic solvent:- Quantity of corn or fish oil vehicle, if used, per unit mass of fish food:- Chemical name of vehicle (organic solvent), if used:- Method of mixing:- Equilibration time:- Method for removal of solvent, if used:**Option 2 Type "Sediment"** PREPARATION OF SPIKED SEDIMENT - Pooling or mixing of different substrates: - Method of mixing:  - Details of spiking:  - Equilibration time: - Equilibration conditions: - Controls:  - Chemical name of vehicle (organic solvent, emulsifier or dispersant):  - Concentration of vehicle in test medium (stock solution and final test solution):  - Evaporation of vehicle before use:   PREPARATION OF SPIKED WATER - Details of spiking:  - Controls:  - Chemical name of vehicle (organic solvent, emulsifier or dispersant):  - Concentration of vehicle in final test solution: | Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) thereof. |  |
|  | **Test organisms** | **Header 2** |  |  |  |
|  | Test organisms (species) | List (picklist)Display: Basic | **Picklist values:**- Alburnus albidus costa - [fish]- Alburnus alburnus - [fish]- Alburnus lucidus - [fish]- Alburnus sp. - [fish]- Alosa pseudobarengus - [fish]- Anchoa mitchilli - [fish]- Anguilla anguilla - [fish]- Anguilla japonica - [fish]- Anguilla rostrata - [fish]- Anguilla sp. - [fish]- Barbus barbus - [fish]- Brevoortia patronus - [fish]- Brevoortia tyrannus - [fish]- Carassius auratus - [fish]- Carassius carassius - [fish]- Carassius sp. - [fish]- Carassius vulgaris - [fish]- Catostomus commersoni - [fish]- Centropomus undecimalis - [fish]- Centropristis striata - [fish]- Clupea harengus - [fish]- Colisa fasciatus - [fish]- Coregonus artedii - [fish]- Coregonus clupeaformis - [fish]- Ctenopharyngodon idella - [fish]- Cymatogaster aggregata - [fish]- Cynoscion nebulosus - [fish]- Cyprinodon sp. - [fish]- Cyprinodon variegatus - [fish]- Cyprinus auratus - [fish]- Cyprinus carassius - [fish]- Cyprinus carpio - [fish]- Cyprinus sp. - [fish]- Danio rerio (previous name: Brachydanio rerio) - [fish]- Dorosoma petenese - [fish]- Esox lucius - [fish]- Esox masquinongi - [fish]- Esox niger - [fish]- Esox sp. - [fish]- Fundulus confluentus - [fish]- Fundulus diaphanus - [fish]- Fundulus grandis - [fish]- Fundulus heteroclitus - [fish]- Fundulus jenkinsi - [fish]- Fundulus lucidae - [fish]- Fundulus majalis - [fish]- Fundulus similis - [fish]- Fundulus sp. - [fish]- Gadus morrhua - [fish]- Gambusia affinis - [fish]- Gasterosteus aculeatus - [fish]- Gaus mexlaughs - [fish]- Harengula pensacolae - [fish]- Ictalurus catus - [fish]- Ictalurus furcatus - [fish]- Ictalurus melas - [fish]- Ictalurus natalis - [fish]- Ictalurus nebulosus - [fish]- Ictalurus punctatus - [fish]- Ictalurus sp. - [fish]- Idus idus - [fish]- Jordanella floridae - [fish]- Lagodon rhomboides - [fish]- Lebistes reticulatus - [fish]- Leiostomus xanthurus - [fish]- Lepomis auritus - [fish]- Lepomis cyanellus - [fish]- Lepomis gibbosus - [fish]- Lepomis humilis - [fish]- Lepomis macrochirus - [fish]- Lepomis microlophus - [fish]- Lepomis pallidus - [fish]- Lepomis sp. - [fish]- Leuciscus cephalus cabeda rissa - [fish]- Leuciscus idus - [fish]- Leuciscus idus melanotus - [fish]- Leuciscus rutilus - [fish]- Leuciscus sp. - [fish]- Limanda aspera - [fish]- Limanda limanda - [fish]- Limanda sp. - [fish]- Menidia beryllina - [fish]- Menidia menidia - [fish]- Menidia peninsulae - [fish]- Menidia sp. - [fish]- Micropogon undulatus - [fish]- Micropterus dolomieui - [fish]- Micropterus salmoides - [fish]- Micropterus sp. - [fish]- Misgurnus anguillicaudatus - [fish]- Morone chrysops - [fish]- Morone saxatilis - [fish]- Morone sp. - [fish]- Mugil cephalus - [fish]- Mugil curema - [fish]- Mugil sp. - [fish]- Notropis atherinoides - [fish]- Oncorhynchus gorbuscha - [fish]- Oncorhynchus keta - [fish]- Oncorhynchus kisutch - [fish]- Oncorhynchus mykiss (previous name: Salmo gairdneri) - [fish]- Oncorhynchus nerka - [fish]- Oncorhynchus nerka kennerlyi - [fish]- Oncorhynchus sp. - [fish]- Oncorhynchus tschawytscha - [fish]- Oryzias latipes - [fish]- Osmerus mordax - [fish]- Parophrys vetulus - [fish]- Perca flavescens - [fish]- Perca fluviatilis - [fish]- Perca sp. - [fish]- Petromyzon fluviatilis - [fish]- Petromyzon marinus - [fish]- Petromyzon sp. - [fish]- Phoxinus laevis - [fish]- Phoxinus phoxinus - [fish]- Phoxinus sp. - [fish]- Pimephales notatus - [fish]- Pimephales promelas - [fish]- Pimephales sp. - [fish]- Platypoecilus maculatus - [fish]- Pleuronectes platessa - [fish]- Poecilia latipinna - [fish]- Poecilia reticulata - [fish]- Poecilia sp. - [fish]- Pogonias cromis - [fish]- Pomatomus saltatrix - [fish]- Pomoxis annularis - [fish]- Pomoxis nigromaculatus - [fish]- Prosopium williamsoni - [fish]- Pseudopleuronectes americanus - [fish]- Ptychocheilus oregonensis - [fish]- Rasbora heteromorpha - [fish]- Rhodeus sericeus - [fish]- Roccus americanus - [fish]- Rutilus rutilus - [fish]- Salmo aquabonita - [fish]- Salmo clarki - [fish]- Salmo irideus - [fish]- Salmo salar - [fish]- Salmo sp. - [fish]- Salmo trutta - [fish]- Salvelinus alpinus - [fish]- Salvelinus fontinalis - [fish]- Salvelinus malma - [fish]- Salvelinus namaycush - [fish]- Salvelinus sp. - [fish]- Sardinops sagax - [fish]- Sarotherodon mossambicus - [fish]- Scardinius erythrophthalmus - [fish]- Sciaenops ocellata - [fish]- Semolitus atromaculatus - [fish]- Sphaeroidus maculatus - [fish]- Stizostedion canadense - [fish]- Stizostedion v. vitreum - [fish]- Tinca sp. - [fish]- Tinca tinca - [fish]- Tinca vulgaris - [fish]- Trutta iridea - [fish]- Daphnia magna - [invertebrate]- Daphnia cucullata - [invertebrate]- Daphnia pulex - [invertebrate]- Daphnia pulicaria - [invertebrate]- Daphnia sp. - [invertebrate]- Americamysis bahia - [invertebrate]- Artemia salina - [invertebrate]- Artemia sp. - [invertebrate]- Asellus intermedius - [invertebrate]- Asellus sp. - [invertebrate]- Ceriodaphnia dubia - [invertebrate]- Ceriodaphnia sp. - [invertebrate]- Crangon crangon - [invertebrate]- Chironomus dilutus (previous name: Chironomus tentans) - [invertebrate]- Chironomus riparius - [invertebrate]- Chironomus sp. - [invertebrate]- Chironomus yoshimatsui - [invertebrate]- Crangon septemspinosa - [invertebrate]- Crangon sp. - [invertebrate]- Elasmopus pectenicrus - [invertebrate]- Elasmopus sp. - [invertebrate]- Gammarus fasciatus - [invertebrate]- Gammarus lacustris - [invertebrate]- Gammarus minus - [invertebrate]- Gammarus olivii - [invertebrate]- Gammarus pulex - [invertebrate]- Gammarus sp. - [invertebrate]- Idotea balthica basteri - [invertebrate]- Hexagenia sp. - [invertebrate]- Hyalella azteca - [invertebrate]- Hyalella sp. - [invertebrate]- Nitocra spinipes - [invertebrate]- Lumbriculus variegatus - [invertebrate]- Pagurus logicarpus - [invertebrate]- Palaemonetes pugio - [invertebrate]- Palaemonetes vulgaris - [invertebrate]- Simocephalus serrulatus - [invertebrate]- Sphaeroma serratum - [invertebrate]- other aquatic arthropod: - [invertebrate]- other aquatic crustacea: - [invertebrate]- other aquatic mollusc: - [invertebrate]- other aquatic worm: - [invertebrate]- Agmenellum quadruplicatum - [algae / cyanobacteria]- Anabaena cylindrica - [algae / cyanobacteria]- Anabaena doloilum - [algae / cyanobacteria]- Anabaena flos-aquae - [algae / cyanobacteria]- Anabaena inaequalis - [algae / cyanobacteria]- Anabaena sp. - [algae / cyanobacteria]- Anabaena variabilis - [algae / cyanobacteria]- Anacystis aeruginosa - [algae / cyanobacteria]- Anacystis sp. - [algae / cyanobacteria]- Ankistrodesmus bibraianus - [algae / cyanobacteria]- Ankistrodesmus falcatus - [algae / cyanobacteria]- Ankistrodesmus minutissimus - [algae / cyanobacteria]- Ankistrodesmus sp. - [algae / cyanobacteria]- Chlamydomonas reinhardtii - [algae / cyanobacteria]- Chlamydomonas sp. - [algae / cyanobacteria]- Chlorella emersonii - [algae / cyanobacteria]- Chlorella fusca - [algae / cyanobacteria]- Chlorella mucosa - [algae / cyanobacteria]- Chlorella pyrenoidosa - [algae / cyanobacteria]- Chlorella sp. - [algae / cyanobacteria]- Chlorella vulgaris - [algae / cyanobacteria]- Chlorococcum sp. - [algae / cyanobacteria]- Cyclotella cryptica - [algae / cyanobacteria]- Cyclotella sp. - [algae / cyanobacteria]- Desmodesmus subspicatus (previous name: Scenedesmus subspicatus) - [algae / cyanobacteria]- Dictosphaerium pulchellum - [algae / cyanobacteria]- Dictosphaerium sp. - [algae / cyanobacteria]- Dunaliella bioculata - [algae / cyanobacteria]- Dunaliella salina - [algae / cyanobacteria]- Dunaliella sp. - [algae / cyanobacteria]- Dunaliella tertiolecta - [algae / cyanobacteria]- Euglena gracilis - [algae / cyanobacteria]- Euglena sp. - [algae / cyanobacteria]- Gyrodinium sp. - [algae / cyanobacteria]- Haematococcus pluvialis - [algae / cyanobacteria]- Haematococcus sp. - [algae / cyanobacteria]- Hormidium flaccidum - [algae / cyanobacteria]- Hormidium sp. - [algae / cyanobacteria]- Microcystis aeruginosa - [algae / cyanobacteria]- Microcystis sp. - [algae / cyanobacteria]- Monoraphidium griffithii - [algae / cyanobacteria]- Monoraphidium sp. - [algae / cyanobacteria]- Navicula pelliculosa - [algae / cyanobacteria]- Navicula seminulum - [algae / cyanobacteria]- Navicula sp. - [algae / cyanobacteria]- Nitella sp. - [algae / cyanobacteria]- Nitscheria linearis - [algae / cyanobacteria]- Nitzschia palea - [algae / cyanobacteria]- Nitzschia sp. - [algae / cyanobacteria]- Oscillatoria sp. - [algae / cyanobacteria]- Phaeodactylum sp. - [algae / cyanobacteria]- Phaeodactylum tricornutum - [algae / cyanobacteria]- Phormidium tenue - [algae / cyanobacteria]- Raphidocelis subcapitata (previous names: Pseudokirchneriella subcapitata, Selenastrum capricornutum) - [algae / cyanobacteria]- Scenedesmus acutus - [algae / cyanobacteria]- Scenedesmus capricornutum - [algae / cyanobacteria]- Scenedesmus pannonicus - [algae / cyanobacteria]- Scenedesmus quadricauda - [algae / cyanobacteria]- Scenedesmus sp. - [algae / cyanobacteria]- Selenastrum sp. - [algae / cyanobacteria]- Skeletonema costatum - [algae / cyanobacteria]- Skeletonema sp. - [algae / cyanobacteria]- Spirulina platensis - [algae / cyanobacteria]- Spirulina sp. - [algae / cyanobacteria]- Stichococcus sp. - [algae / cyanobacteria]- Synechococcus elongatus - [algae / cyanobacteria]- Lemna aequinoctialis - [aquatic plant]- Lemna gibba - [aquatic plant]- Lemna major - [aquatic plant]- Lemna minor - [aquatic plant]- Lemna paucicostata - [aquatic plant]- Lemna perpusilla - [aquatic plant]- Lemna sp. - [aquatic plant]- Lemna trisulca - [aquatic plant]- Lemna valdiviana - [aquatic plant]- other:- not specified | Select species from picklist. If not available, select 'other' and enter name of organism (species). |  |
|  | Details on test organisms | Text templateDisplay: Detailed | **Freetext template:**TEST ORGANISM- Common name:- Strain:- Source:- Age at study initiation (mean and range, SD):- Length at study initiation (length definition, mean, range and SD):- Weight at study initiation (mean and range, SD):- Weight at termination (mean and range, SD):- Method of breeding:- Lipid content at test initiation (mean and range, SD):- Health status:- Description of housing/holding area:- Feeding during test - Food type:  - Amount:  - Frequency:  ACCLIMATION- Acclimation period:- Acclimation conditions (same as test or not):- Type and amount of food:- Feeding frequency:- Health during acclimation (any mortality observed): | Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof. |  |
|  | **Study design** | **Header 2** |  |  |  |
|  | Route of exposure | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- aqueous- sediment- feed- other: | Indicate if exposure was to aquatic medium, sediment or through feed (i.e. dietary exposure). |  |
|  | Justification for method | List sup. (picklist with remarks)Display: Detailed | **Picklist values:**- minimised test method used to support BCF estimates based on Kow- minimised test method used to support BCF estimates based on QSAR- minimised test method used for following reason:- dietary exposure method used because stable, measurable water concentrations cannot be maintained- dietary exposure method used because adequate body burdens cannot be achieved within 60 days of exposure- dietary exposure method used for following reason: - [./.]- aqueous exposure method used for following reason: - [./.]- other: | As appropriate provide a justification for the exposure method chosen, i.e. whether to conduct an aqueous or dietary exposure test, and in what set. Refer to the criteria specified in the relevant test guideline and/or regulatory framework.The picklist allows for selecting either one of the pre-defined phrases or 'other:'. Free text explanation can also be entered in the supplementary remarks field. |  |
|  | Test type | List (picklist)Display: Basic | **Picklist values:**- static- semi-static- flow-through- field study- other:- not specified | Select appropriate test type. |  |
|  | Water / sediment media type | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- natural water: freshwater- natural water: marine- natural water: brackish- natural water- natural water / sediment: freshwater- natural water / sediment: marine- natural water / sediment: brackish- natural water / sediment- natural sediment: freshwater- natural sediment: marine- natural sediment: brackish- natural sediment- artificial sediment- natural soil- mixture of sewage, soil and natural water- other:- not specified | Indicate the water or sediment media type. |  |
|  | Total exposure / uptake duration | Numeric range (decimal with picklist)Display: Basic | **Lower numeric field [xx]:**- >- >=- ca.**Upper numeric field [xx]:**- <- <=- ca.**Picklist values:**- min- h- d- wk | Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable. |  |
|  | Total depuration duration | Numeric range (decimal with picklist)Display: Basic | **Lower numeric field [xx]:**- >- >=- ca.**Upper numeric field [xx]:**- <- <=- ca.**Picklist values:**- min- h- d- wk | Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable. |  |
|  | **Test conditions** | **Header 2** |  |  |  |
|  | Hardness | Text (2,000 char.)Display: Detailed |  | Indicate water hardness as mg/L calcium carbonate equivalent values measured in the treatment and control solutions during test. Include range, mean, standard deviation and unit. Alternatively refer to table (e.g. 'see table no. 2') if the test conditions are presented in tabular form in the rich text editor field. |  |
|  | Test temperature | Text (2,000 char.)Display: Detailed |  | Indicate test temperature values measured in the treatment and control solutions during test. Include range, mean, standard deviation and unit. As appropriate state the location (e.g. water bath, test chambers) and type of measurement (e.g. continuous monitoring). Alternatively refer to table (e.g. 'see table no. 2') if the test conditions are presented in tabular form in the rich text editor field. |  |
|  | pH | Text (2,000 char.)Display: Detailed |  | Indicate pH values measured in the treatment and control solutions during test. Include range, mean, standard deviation and unit. Indicate how mean pH is to be obtained. Alternatively refer to table (e.g. 'see table no. 2') if the test conditions are presented in tabular form in the rich text editor field. |  |
|  | Dissolved oxygen | Text (2,000 char.)Display: Detailed |  | Indicate dissolved oxygen values measured in the treatment and control solutions during test. Include range, mean, standard deviation and unit. Alternatively refer to table (e.g. 'see table no. 2' ) if the test conditions are presented in tabular form in the rich text editor field. |  |
|  | TOC | Text (2,000 char.)Display: Detailed |  | Indicate TOC (total organic carbon) values measured during test. Include range, mean, standard deviation and unit. Alternatively refer to table (e.g. 'see table no. 2') if the test conditions are presented in tabular form in the rich text editor field. |  |
|  | Salinity | Text (2,000 char.)Display: Detailed |  | For marine studies, indicate salinity (if relevant) values measured in the treatment and control solutions during test. Include range, mean, standard deviation and unit. Alternatively refer to table (e.g. 'see table no. 2') if the test conditions are presented in tabular form in the rich text editor field. |  |
|  | Conductivity | Text (2,000 char.)Display: Detailed |  | Indicate conductivity values measured in the treatment and control solutions during test. Include range, mean, standard deviation and unit. Alternatively refer to table (e.g. 'see table no. 2' ) if the test conditions are presented in tabular form in the rich text editor field. |  |
|  | Details on test conditions | Text templateDisplay: Detailed | **Freetext template:Option 1 Type 'aqueous', including dietary exposure**TEST SYSTEM- Test vessel:- Type (delete if not applicable): open / closed- Material, size, headspace, fill volume:- Aeration:- Type of flow-through (e.g. peristaltic or proportional diluter):- Renewal rate of test solution (frequency/flow rate):- No. of organisms per vessel:- No. of vessels per concentration (replicates):- No. of vessels per control / vehicle control (replicates):- Biomass loading rate:TEST MEDIUM / WATER PARAMETERS- Source/preparation of dilution water:- Particulate matter:- Metals:- Pesticides:- Chlorine:- Alkalinity:- Ca/mg ratio:- Conductance:- Holding medium different from test medium:- Intervals of water quality measurement:- Intervals of test medium replacement:OTHER TEST CONDITIONS- Adjustment of pH:- Photoperiod:- Light intensity:- For OECD 305 part III (dietary exposure fish bioaccumulation), overall daily feeding rate used in the study:- For OECD 305 part III (dietary exposure fish bioaccumulation), number of feeds per day (number of feeds daily ration split between):- For OECD 305 part III (dietary exposure fish bioaccumulation), overall lipid content of spiked food before test start taking into account the contribution from the corn or fish oil vehicle, if used:- For OECD 305 part III (dietary exposure fish bioaccumulation), overall lipid content of spiked food after end of exposure taking into account the contribution from the corn or fish oil vehicle, if used:RANGE-FINDING / PRELIMINARY STUDY- Test concentrations:- Results used to determine the conditions for the definitive study:- Other justification for choice of test concentrations:**Option 2 Type 'sediment'**TEST SYSTEM- Test container (material, size):- Water volume:- Sediment mass and volume:- Aeration:- Type of flow-through (e.g. peristaltic or proportional diluter):- Renewal rate of test solution (frequency/flow rate):- No. of organisms per container (treatment):- No. of replicates per treatment group:- No. of replicates per control / vehicle control:- Sediment to water ratio:- Biomass loading rate:SOURCE AND PROPERTIES OF SUBSTRATE- Geographical reference of sampling site (latitude, longitude):- History of site:- Vegetation cover:- Treatments with pesticides or fertilizers:- Accidental contamination:- Other:- Composition (if artificial substrate):- pH of pore water (natural sediments)- Ammonia concentration of pore water (natural sediments)- Organic carbon (%):- Particle size distribution (percent sand, silt, and clay):- Ammonia concentration in pore water:- Water content (%):- Dry weight-to-wet weight ratioOTHER TEST CONDITIONS- Adjustment of pH:- Photoperiod:- Light intensity:- Equilibration time:- Feeding:- Sediment to organism ratio:- Water to organism ratio:VEHICLE CONTROL PERFORMED: yes/noRANGE-FINDING / PRELIMINARY STUDY- Test concentrations:- Results used to determine the conditions for the definitive study:- Other justification for choice of test concentrations: | Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) thereof. |  |
|  | Nominal and measured concentrations | Text (2,000 char.)Display: Basic |  | List nominal and, if available, measured test concentrations (with unit, i.e. µg/l, mg/l, g/l, mmol/l, mol/l, µmol/l, mg/kg fish food or other) for all sampling times. As appropriate tabulate nominal vs. measured concentrations; include table(s) in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1').Use alternative predefined tables if data for both the technical end product and the active ingredient are to be recorded.If exposure is through diet, provide the nominal and measured dietary concentrations and the doses applied.Note: Specific tables may be required. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof. |  |
|  | Reference substance (positive control) | List sup. (picklist with remarks)Display: Detailed | **Picklist values:**- yes- no- not specified- not required | Indicate if a positive control was tested, i.e. a reference substance with known bioaccumulation potential. If yes, include the identity of the substance(s) and the concentrations in the supplementary remarks field. |  |
|  | Details on estimation of bioconcentration | Text templateDisplay: Basic | **Freetext template:**BASIS INFORMATION - Measured/calculated logPow:  - Results from toxicokinetic study: - Results from residue study: - Monitoring data:  BASIS FOR CALCULATION OF BCF - Estimation software: - Result based on measured log Pow of: - Result based on calculated log Pow of: | If the intrinsic potential of the test substance for bioconcentration was estimated, indicate physico-chemical properties, experimental toxicokinetic/residue studies or monitoring data the bioconcentration potential was based on.Indicate the applied software (e.g. BCFWIN, v 2.13) and the basis for BCF calculation (e.g. measured log Pow). |  |
|  | **Any other information on materials and methods incl. tables** | **Header 2** |  |  |  |
|  |  | Text (rich-text area)Display: Basic |  | In this field, you can enter any information on materials and methods, for which no distinct field is available, or transfer free text from other databases. You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet document, provided it was converted to the HTML format. You can also upload any htm or html document.Note: One rich text editor field each is provided for the MATERIALS AND METHODS and RESULTS section. In addition the fields 'Overall remarks' and 'Executive summary' allow rich text entry. |  |
|  | **Results and discussion** | **Header 1** |  |  |  |
|  | **Lipid content** | **Block of fields (repeatable) Start** |  | Indicate the lipid content of test organisms with unit. If appropriate specify the time point at which the measurement was made, e.g. start or end of experiment.Copy this block of fields if measuring lipid content at end of uptake and end of depuration phases.Copy this block of fields for specifying the lipid content ratio in % if required. |  |
|  | Lipid content | Numeric range (decimal with picklist)Display: Basic | **Lower numeric field [xx]:**- >- >=- ca.**Upper numeric field [xx]:**- <- <=- ca.**Picklist values:**- µg/kg bw d.w.- mg/kg bw d.w.- µg/kg bw w.w.- mg/kg bw w.w.- %- other: | Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable. |  |
|  | Time point | List (picklist)Display: Basic | **Picklist values:**- start of exposure- end of exposure- other: | Select from drop-down list. |  |
|  | Remarks on result | List sup. (picklist with remarks - 2,000 char.)Display: Basic | **Picklist values:**- not determinable- not determinable because of methodological limitations- not measured/tested- other: | This field can be used for:- giving a qualitative description of results in addition to or if no numeric value(s) were derived;- giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or- entering any additional information by selecting 'other:'. |  |
|  | **Lipid content** | **Block of fields (repeatable) End** |  |  |  |
|  | **Bioaccumulation factor** | **Block of fields (repeatable) Start** |  | This repeatable block of fields allows reporting of the aqueous bioconcentration factors, i.e. the steady-state BCFs and/or the kinetic BCFk. For sediment-dwelling organisms BAF (bioaccumulation factor), BSAF (biota-sediment accumulation factor) and/or pore water BCFs can be specified. Also dietary biomagnifications factors (BMF), e.g. from fish dietary studies, can be recorded.For dietary biomagnification factor (dietary BMF) according to the OECD 305 part III test, the calculated assimilation efficiency (α) should also be stated.As appropriate or requested by the regulatory programme include table(s) in the rich text field 'Any other information on results incl. tables' showing the bioaccumulation/ bioconcentration factors measured at different time points and concentrations in the water. Upload predefined or other appropriate table(s) if any, and tailor it/them to your needs. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). |  |
|  | Key result | Check boxDisplay: Basic |  | Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on how to use this field. |  |
|  | Conc. / dose | Numeric range (decimal with picklist)Display: Basic | **Lower numeric field [xx]:**- >- >=- ca.**Upper numeric field [xx]:**- <- <=- ca.**Picklist values:**- ng/kg sediment dw- µg/kg sediment dw- mg/kg sediment dw- ng/g food- µg/g food- mg/g food- ng/L- µg/L- mg/L- g/L- other: | Give the concentration in surrounding water (and/or sediment, if sediment study) or the dose level applied (if feeding study). If more than one concentration or dose was tested for which different bioaccumulation factors are reported, e.g. for high and low concentration levels, multiply this block of fields. |  |
|  | Temp. | Numeric range (decimal with picklist)Display: Basic | **Lower numeric field [xx]:**- >- >=- ca.**Upper numeric field [xx]:**- <- <=- ca.**Picklist values:**- °C- K- °F | Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable. |  |
|  | pH | Numeric (decimal)Display: Basic |  | Enter numeric value. |  |
|  | Type | List (picklist)Display: Basic | **Picklist values:**- BAF- BCF- BMF- BSAF- other: | Indicate the reported bioaccumulation value, i.e. either BCF (bioconcentration factor which accounts for substance intake from the surrounding water or pore water if sediment study only), BAF (bioaccumulation factor which accounts for substance intake from both food and surrounding water/sediment), BSAF (biota-sediment accumulation factor), BMF (dietary biomagnification factor, i.e. the ratio between the relative concentration in a predatory animal and the concentration in (part of) its prey or the kinetically derived value) or other (to be specified). |  |
|  | Value | Numeric range (decimal with picklist)Display: Basic | **Lower numeric field [xx]:**- >- >=- ca.**Upper numeric field [xx]:**- <- <=- ca.**Picklist values:**- dimensionless- L/kg- m³/kg- other: | Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable. |  |
|  | Basis | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- whole body w.w.- whole body d.w.- organ w.w.- organ d.w.- edible fraction- non-edible fraction- normalised lipid fraction- total lipid content- not specified- other: | From drop-down list, select the basis for the bioaccumulation value, i.e. expressed in relation to the whole body, the total lipid content or specific tissues of the test organisms (w.w. = wet weight; d.w. = dry weight).Note: For OECD TG 305-III dietary method, the result is reported relative to the ratio of fish lipid: food lipid. |  |
|  | Time of plateau | Numeric (decimal including unit)Display: Basic | **Unit [xx]:**- min- h- d- wk | If applicable, indicate time at which plateau was reached (for tissue concentration). |  |
|  | Calculation basis | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- steady state- kinetic- kinetic, corrected for growth- other: | If the Bioaccumulation value was not calculated at steady state, select 'kinetic:' and briefly specify using the supplementary remarks field (e.g. 'kinetic: steady state at 80% of equilibrium' or, for the dietary exposure OECD 305 method, the values of assimilation efficiency, fish concentration at end of depuration etc used in the calculations). |  |
|  | Remarks on result | List sup. (picklist with remarks - 2,000 char.)Display: Basic | **Picklist values:**- not determinable- not determinable because of methodological limitations- not measured/tested- other: | This field can be used for:- giving a qualitative description of results in addition to or if no numeric value(s) were derived;- giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or- entering any additional information by selecting 'other:', e.g. for indicating if bioconcentration / bioaccumulation is based on parent compound instead of radioactivity. |  |
|  | **Bioaccumulation factor** | **Block of fields (repeatable) End** |  |  |  |
|  | **Depuration** | **Block of fields (repeatable) Start** |  | Indicate if clearance of test substance or metabolites from test organisms was observed; give depuration time required for clearance of 50% (DT50), 90% (DT90) and or any other percent of residues. |  |
|  | Key result | Check boxDisplay: Basic |  | Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on how to use this field. |  |
|  | Elimination | List (picklist)Display: Basic | **Picklist values:**- yes- no- not specified | Indicate whether elimination of test substance or metabolites occurred or not. |  |
|  | Parameter | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- DT50- DT90- other: | Indicate to which endpoint type the effect concentration refers, e.g. DT50. |  |
|  | Depuration time (DT) | Numeric (decimal including unit)Display: Basic | **Unit [xx]:**- min- h- d- wk | Enter numeric value. |  |
|  | Remarks on result | List sup. (picklist with remarks - 2,000 char.)Display: Basic | **Picklist values:**- not determinable- not determinable because of methodological limitations- not measured/tested- other: | This field can be used for:- giving a qualitative description of results in addition to or if no numeric value(s) were derived;- giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or- entering any additional information by selecting 'other:'. |  |
|  | **Depuration** | **Block of fields (repeatable) End** |  |  |  |
|  | **Rate constants** | **Block of fields (repeatable) Start** |  | Provide the numeric values of relevant rate constants as appropriate and/or give an explanation in field ' Explanation of result'. |  |
|  | Key result | Check boxDisplay: Basic |  | Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on how to use this field. |  |
|  | Rate constant | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- growth rate constant (d-1)- overall uptake rate constant (L kg-1 d-1)- overall depuration rate constant (d-1)- growth-corrected depuration rate constant (d-1)- growth-corrected half-life (d)- other: | Select the rate constant, e.g. ' growth rate constant (d-1)'. Additional free text explanation can be entered in the supplementary remarks field. |  |
|  | Value | Numeric (decimal)Display: Basic |  | Enter numeric value. |  |
|  | Remarks on result | List sup. (picklist with remarks - 2,000 char.)Display: Basic | **Picklist values:**- not determinable- not determinable because of methodological limitations- not measured/tested- other: | This field can be used for:- giving a qualitative description of results in addition to or if no numeric value(s) were derived;- giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or- entering any additional information by selecting 'other:'. |  |
|  | **Rate constants** | **Block of fields (repeatable) End** |  |  |  |
|  | Details on kinetic parameters | Text templateDisplay: Detailed | **Freetext template:**- Uptake rate constant k(s):- Depuration rate constant k(e):- Indication of bi- or multiphasic kinetics:- Computation / data analysis: | Give values (including 95 % confidence limits and standard deviations) for the uptake and depuration rate constants (all expressed in relation to whole body, total lipid content or specific tissues of the test organisms); give relevant details on computation/data analysis. |  |
|  | Metabolites | Text (32,768 char.)Display: Detailed |  | If identified, include table(s) in the rich text field 'Any other information on results incl. tables' with data on any metabolites of the test substance accumulated in test organisms (total) and specific tissues thereof (e.g. lipid) (at least those, accounting for > 10 % of residues). Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). |  |
|  | Metabolites | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- no- not measured- yes- not specified |  |  |
|  | **Identity of metabolites** | **Block of fields (repeatable) Start** |  | If identified, indicate the identity of metabolites of the test substance accumulated in the test organisms, using an appropriate identifier, e.g. CAS number, CAS name, IUPAC name, SMILES code, molecular formula, structural formula. Copy this block of fields for each relevant substance.Any further details on metabolites can be provided in field 'Any other information on materials and methods incl. tables'. |  |
|  | ID no. | List (picklist)Display: Basic | **Picklist values:**- #1- #2- #3- #4- #5- #6- #7- #8- #9- #10- #11- #12- #13- #14- #15- #16- #17- #18- #19- #20- #21- #22- #23- #24- #25- #26- #27- #28- #29- #30- #31- #32- #33- #34- #35- #36- #37- #38- #39- #40- other: | For easier distinction, you can assign consecutive numbers to the test substance (i.e. #1) and to each metabolite (i.e. #2, #3, etc.). |  |
|  | Identity of compound | Link to entity (single)Display: Basic |  | Indicate the identity of the compound (metabolite or test substance) using an appropriate identifier, e.g. CAS number, CAS name, IUPAC name, SMILES code, molecular formula, structural formula. Click the Link button to navigate to the Substances Inventory and select the relevant substance name. If not available in the inventory, create a new one. | **Cross-reference:**REFERENCE\_SUBSTANCE |
|  | Parent compound(s) | Link to entity (multiple)Display: Basic |  | If the compound is a metabolite, link to the identity of the substance that is characterised as the parent of this metabolite. Link to multiple parent substances if applicable.Click the Link button to navigate to the Substances Inventory and select the relevant substance name. If not available in the inventory, create a new one. | **Cross-reference:**REFERENCE\_SUBSTANCE |
|  | Maximum occurrence | Numeric (decimal including unit)Display: Basic | **Unit [xx]:**- %- ppm | Indicate the maximum occurrence of the total accumulated metabolite in the test organism. |  |
|  | **Identity of metabolites** | **Block of fields (repeatable) End** |  |  |  |
|  | Results with reference substance (positive control) | Text (2,000 char.)Display: Detailed |  | If reference substance(s) was/were tested, indicate whether the results with it/them are valid. |  |
|  | Details on results | Text templateDisplay: Detailed | **Freetext template:**- Mortality of test organisms:- Behavioural abnormalities:- Observations on feeding behavior:- Observations on body length and weight:- Reproduction during test period:- Other biological observations:- Organ specific bioaccumulation:- Bound residues forming a plateau:- Mortality and/or behavioural abnormalities of control:- Loss of test substance during test period:- Non-eliminated residues (NER) at the end of elimination phase:- Results with vehicle control: | Report any other relevant results using freetext template as appropriate. Indicate any results related to the chemical properties of the test material. Compare the results for the test substance with that for the reference substance.Upload predefined or other appropriate tables(s) if any, and tailor it/them to your needs. |  |
|  | Reported statistics | Text (2,000 char.)Display: Detailed |  | Indicate the parameters analysed, the statistical method used and the statistical test performed. |  |
|  | **Any other information on results incl. tables** | **Header 2** |  |  |  |
|  |  | Text (rich-text area)Display: Basic |  | In this field, you can enter any other remarks on results. You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet document, provided it was converted to the HTML format.Note: One rich text editor field each is provided for the MATERIALS AND METHODS and RESULTS section. In addition the fields 'Overall remarks' and 'Executive summary' allow rich text entry. |  |
|  | **Overall remarks, attachments** | **Header 1** |  |  |  |
|  | Overall remarks | Text (rich-text area)Display: Basic |  | In this field, you can enter any overall remarks or transfer free text from other databases. You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet document, provided it was converted to the HTML format. You can also upload any htm or html document.Note: One rich text editor field each is provided for the MATERIALS AND METHODS and RESULTS section. In addition the fields 'Overall remarks' and 'Executive summary' allow rich text entry. |  |
|  | **Attachments** | **Block of fields (repeatable) Start** |  | Attach any background document that cannot be inserted in any rich text editor field, particularly image files (e.g. an image of a structural formula).Copy this block of fields for attaching more than one file. |  |
|  | Type | List (picklist)Display: Basic | **Picklist values:**- full study report- illustration (picture/graph)- other: | Specify the type of attachment inserted, for example the 'full study report'. |  |
|  | Attached (confidential) document | Attachment (single)Display: Basic (Confidential) |  | An electronic copy of the full study report or other documents can be attached as Word, pdf or other file types. |  |
|  | Attached (sanitised) documents for publication | Attachment (single)Display: Basic |  | An electronic copy of a public (non-confidential) version of the full study report or other relevant documents can be attached. This attachment should be sanitised if needed. |  |
|  | Remarks | Text (255 char.)Display: Basic |  | As appropriate, include remarks, e.g. a short description of the content of the attached document if the file name is not self-explanatory. |  |
|  | **Attachments** | **Block of fields (repeatable) End** |  |  |  |
|  | **Applicant's summary and conclusion** | **Header 1** |  |  |  |
|  | Validity criteria fulfilled | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- yes- no- not specified- not applicable | State whether validity criteria in the test guideline have been fulfilled or not. Use supplementary remarks field to state the criteria and supporting information.Clearly indicate if the criteria used are not consistent with those given by the test guideline. If so, give justification in field 'Rationale for reliability incl. deficiencies' as to why this study summary is considered reliable. |  |
|  | Conclusions | Text (32,768 char.)Display: Basic |  | Enter any conclusions if applicable in addition to the information given in fields 'Key results' and 'Interpretation of results' (if any). |  |
|  | Executive summary | Text (rich-text area)Display: Basic |  | If relevant for the respective regulatory programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, copy it from the corresponding document or upload it if provided as htm or html document.Consult the programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) thereof. |  |