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# CRITICAL APPRAISAL TOOLS (CATS) IN ECOTOXICOLOGY

## CALL FOR NOMINATION

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# TABLE OF CONTENT

The CATs project in a nutshell



Principles of the project



Deliverables of the project



Purpose of this call for nomination



Home / Publications / Proposal of critical appraisal tools for the evaluation of ecotoxicology studies

## Proposal of critical appraisal tools for the evaluation of ecotoxicology studies

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# CATS PROJECT IN A NUTSHELL

- The project OC/EFSA/PREV/2020/01 was launched and evaluated in 2020 and started in July 2021
- Project aims at developing critical appraisal tools (CATs) for the evaluation of certain types of studies commonly used in ecotoxicological evaluation of active substances
- EFSA was the contracting authority and a consortium of 4 well-known agencies and organizations working in risk assessment was the contractor:



National institute of Public Health and Environment (RIVM) ( coordinator)

Wageningen Environmental Research ( WENR)



Agency for food, Environmental and Occupational Health and Safety ( ANSES)

German Environmental Agency/ Umweltbundesamt (UBA)

- The project lasted 1-year following the kick-off meeting
- EFSA Ecotox team was involved in crucial revision steps



# THE NEED OF THE PROJECT



Standard and not-standardized studies currently co-exist in the pesticides' dossiers in ecotoxicology



Particularly non-standardized studies can be more complex and of difficult interpretation depending in the level of expertise of the evaluator



Critical Appraisal Tools (CATs) provide a structured approach to

- assess the internal and external validity of individual studies,
- make the assessment more transparent,
- and increase consistence among dossiers.



# CATS FOR DIFFERENT STUDY TYPES

Domain	Studies
Aquatic organisms	Modified exposure studies (tier 2) Mesocosms (tier 3)
Bees	Honeybee brood test (feeding & tent version)
Non-target arthropods other than bees	Extended laboratory studies Aged residue studies Field studies (including the suitability of this CAT for earthworms' field studies)
Residue data (currently relevant for birds and mammals risk assessment)	Supervised residue studies and related kinetics

- Each Excel-based CAT is accompanied by a handbook for guiding the assessor in the evaluation of each criterion.
- Each CAT proposes a final classification of the study in terms of reliability and relevance.
- Experts' judgement might also be applied and if so, it needs to be also justified.

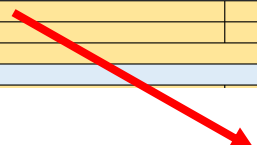


# DELIVERABLES OF THE PROJECT

## Critical Appraisal Tool (CAT) - Reliability assessment of mesocosm studies with aquatic organisms

Mark your evaluation per criterion with an 'x' in the respective box. An explanation of the reasons for the classification should be added to the rationale box.

Number		YES, Criterion fulfilled	Criterion partly fulfilled	NO, Criterion not fulfilled	Criterion not reported	Key criteria	Rationale
	Before evaluating the test, please check the physicochemical characteristics of your compound (handbooks/general sources). What is the solubility, log KOW, pKa? Is the compound volatile? Does it hydrolyse, photolyse, etc.? What is the mode of action (MoA) of the active? What are relevant metabolites and their properties? If any properties could influence study setup or results these should be mentioned in the rationale box in this row.						
	Before evaluating the study, please check whether the test is performed to a guideline method or a guidance document. Also check the geographical location of the study site (only for outdoor field and semi-field studies).						
<b>General information</b>							
G-1	Is a study plan followed? Are deviations from the study plan reported and appropriately justified?						
<b>Validity criteria and control response</b>							
V-1	Are appropriate negative controls included and does the community present in the controls remain representative for a realistic freshwater community (including sensitive and/or vulnerable species) for edge-of-field surface waters during the whole test duration?					Key	
V-2	If a positive control is included, is it appropriate and are effects demonstrated?					Key	
<b>Test item</b>							
T-1	Is the test substance or test item clearly identified? Is the formulation type and amount of active substance reported?					Key	
T-2	Are test results reported for the appropriate form of the compound?					Key	
T-3	Are test results reported for the relevant compounds (i.e. active substance(s) and metabolites)?						
<b>Test location</b>							



### Criterion T-1: Is the test substance or test item clearly identified? Is the formulation type and amount of active substance reported? (Key criterion)

Appraisal	Rationale for appraisal
<b>Criterion fulfilled</b>	The formulated product is clearly identified based on relevant information <b>AND</b>  The formulation type is specified, and the content of active substance(s) and/or other relevant constituents is known and validated by chemical analysis
<b>Criterion partially fulfilled</b>	The formulated product is not clearly identified based on relevant information <b>AND/OR</b>  The formulation type is specified and the amount of active substance and/or constituents in the formulation are known, but not validated by chemical analysis. However, the test item is obtained from a trustworthy source, and the reported composition of the formulated product/formulation is therefore reliable.
<b>Criterion not fulfilled</b>	The formulated product is not clearly identified based on relevant information <b>OR</b>  The amount of active substance and/or constituents in the formulation are unknown and cannot be deduced from trustworthy suppliers' information <b>OR</b>  The content of active substance(s) and/or other relevant constituents are not validated by chemical analysis of the test item solutions.
<b>Justification</b>	The identity of the substance applied (active substance and formulation) has to be reported in detail. Batch number and expiry date should be provided, linked to a certificate of analysis, confirming that the test item was what was applied and that it contained the active substance in the stated quantity.

- The deliverables of the CATs in ecotoxicology can be found [here](#).
- Excel-based CATs and handbooks are under the **supporting information** section.





# Call for nomination

Before being able to implement those tools in the peer-review process, testing is necessary



# PURPOSE OF THIS CALL

- This call for nomination aims at getting ecotoxicology MSs experts in order to test the current CATs in the framework of the assessment of PPP.
- Feedback will be collected and discussed between EFSA and the nominated experts.
- A general meeting will be organized for a final discussion and agreement before the implementation of the final CATs in the peer-review process.
- The call will be launched by the end of the year.
- The general meeting will be scheduled for autumn 2024.





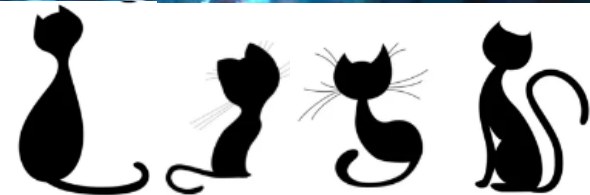
**Call for nomination**

**CATs implementation**

**Any question? Views?!**



**Thank you for your attention!**



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