**EURL ECVAM**

**TEST PRESUBMISSION FORM (TPF)**

**To Allow for a Preliminary Assessment of the Development/Validation Status of a Test Method**

**IMPORTANT NOTE**

**PURPOSE OF THE TPF**

The compilation of this TPF represents the first stage of the EURL ECVAM Test Submission Process and is a mandatory requirement. The completed TPF will allow EURL ECVAM to perform a preliminary assessment of the status of development and/or validation of the test method and its potential relevance. Only if the outcome of this preliminary assessment is positive EURL ECVAM will invite the test method submitter to proceed with the EURL ECVAM test submission process. This involves the completion of EURL ECVAM's more comprehensive “Test Submission Template (TST)”. The information provided via the TST will allow EURL ECVAM to assess whether the submitted test is ready for entering the EURL ECVAM validation process and to select the appropriate sub-process (i.e. prospective validation, retrospective validation, validation based on performance standards, or peer-review). Already during the preliminary assessment phase, EURL ECVAM may share the TPF with its Advisory Structure and international partners, e.g. the EURL ECVAM's Network for Preliminary Assessment of Regulatory Relevance (PARERE), the EURL ECVAM Scientific Advisory Committee (ESAC) and, to the extent possible, with the EURL ECVAM Stakeholder Forum (ESTAF) and the members of the International Cooperation on Alternative Test Methods (ICATM), in view of a) collecting input on the possible prioritisation of the test method and b) possible scientific issues.

**SUBMISSION OF CONFIDENTIAL INFORMATION**

Although EURL ECVAM recognizes that there may be a need to maintain confidentiality of proprietary information, the designation of materials as confidential is discouraged because this limits an open and transparent evaluation. Submission of adequate and complete information will facilitate the EURL ECVAM review process.

If you nevertheless consider some of the information provided in the TPF as confidential (e.g. confidential business information, CBI), please tick the box in section 8. Please, clearly identify those paragraphs where confidential information has been entered and explain why it is considered as such (not more than 100 words per paragraph).

**DISCLAIMER** Please note that a positive assessment of the TPF does not constitute a commitment from EURL ECVAM to proceed to test method validation. EURL ECVAM will regularly prioritise all methods which have been submitted and found to be ready to enter the EURL ECVAM validation process against pre-defined criteria, and decide which test methods/approaches will finally enter validation in the light of available capacities. It is foreseeable that not all submitted test methods can be validated by EURL ECVAM.

**1. GENERAL INFORMATION**

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| **TEST METHOD SUBMITTER** | |
| Organisation/Company |  |
| Department/Faculty/  Institute or Other |  |
| Address |  |
| Postcode |  |
| Town |  |
| Country |  |
| Responsible Contact: | |
| Title | Mr.  Ms.  Dr.  Prof. |
| Surname |  |
| First name |  |
| Function |  |
| Phone |  |
| Fax |  |
| Email |  |
|  | |
| ***ADDITIONAL CONTACT PERSON (OPTIONAL)*** | |
| *Title* | Mr.  Ms.  Dr.  Prof. |
| *Surname* |  |
| *First name* |  |
| *Function* |  |
| *Phone* |  |
| *Fax* |  |
| *Email* |  |
| *If different from above:* | |
| *Organisation/Company* |  |
| *Department/Faculty/*  *Institute or Other* |  |
| *Address* |  |
| *Postcode* |  |
| *Town* |  |
| *Country* |  |

**2. INFORMATION ON THE TEST METHOD**

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| **1.** | **Name of the Test Method** |
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| **2.** | **Abbreviations Used in the Submission** |
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| **3.** | **Test Method Summary** |
| 3.1 | *The test method addresses/informs:*  *Human health effects (e.g. repeated-dose toxicity)*  *Please specify (max. 150 words).*    *Environmental effects (e.g. fish chronic toxicity, bioaccumulation)*  *Please specify (max. 150 words).*    *Other (e.g. quality control of immunobiologicals)*  *Please specify (max. 150 words).* |
| 3.2 | *Briefly describe the mechanistic relevance (e.g. the mechanism of action and its relation to the effect of interest) of the test method (max. 150 words).* |
| 3.3 | *Briefly describe the test system used (e.g. tissue model, specific cells grown to confluence) and its biological relevance in relation to the tissue/organ/species of interest (max. 150 words).* |
| 3.4 | *Briefly describe the readout(s) (e.g. optical density) and endpoint(s) (e.g. cell viability, EC50) measured and their relation to the relevant mechanism(s) of action in the species of interest (max. 150 words).* |
| 3.5 | *Briefly describe the intended purpose (i.e. practical use) of the test method (e.g. regulatory and/or non-regulatory applications) and whether it is intended to be used alone or in combination with other methods (e.g. within an Integrated Approach to Testing and Assessment (IATA) and/or a Defined Approach (DA)) (max. 150 words).* |
| 3.6 | *Does the test method have a positive impact in terms of the 3Rs principle, i.e. does it reduce, refine or replace animal testing (max. 150 words)?* |
| 3.7 | *Does the test method imply the use of animal derived serum (e.g. foetal bovine serum, FBS) and/or of animal derived antibodies (e.g. monoclonal or polyclonal antibodies)? If yes, please justify why animal derived serum and/or animal derived antibodies are used and explain whether you have considered or are considering the possibility to replace them with chemically defined media (i.e. serum-free alternatives) and/or non-animal derived recombinant antibodies (i.e. produced with phage display technology) or other new generation animal-free affinity reagents, such as aptamers, affimers, DARPins, etc. (max. 150 words).* |
| 3.8 | *Describe whether the test method represents an improvement compared to an existing method. Possible improvements include a) better information (e.g. higher accuracy or addressing a mechanism of action), b) effectiveness in terms of throughput (e.g. amenable to high-throughput testing), c) cost (max. 150 words).* |
| 3.9 | *Describe the limitations of the test method. These can include limitations identified through testing (e.g. chemical categories for which the test method does not make reliable and/or relevant predictions), technical limitations (e.g. not applicable to the testing of poorly soluble materials) and/or mechanistic limitations in relation to known modes of action (e.g. skin sensitisation test method only applicable to chemicals binding to cysteine residues) (max. 150 words).* |
| 3.10 | *State if any component of the test method (e.g. protocol, test system, equipment) is patented, copyright protected, trade-marked, registered or treated as confidential business information (CBI). Please specify who is holding the Intellectual Property Rights (max. 150 words).* |

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| **4.** | **Preliminary Assessment of the Protocol’s Optimisation Level** | |
| 4.1 | *Is the test method procedure described precisely, step-by-step, including listing of all necessary reagents and instruments?*  *If yes, please annex the Standard Operating Procedures (SOP) in their current status and indicate the current status of this/these SOP(s) (max. 150 words).* | ***YES***  ***NO*** |
| 4.2 | *Are controls used for the endpoint(s) measured? If yes, please tick the relevant boxes.* | |
| *Positive control*  *If yes, please specify the positive control.* | ***YES***  ***NO*** |
| *Negative control*  *If yes, please specify the negative control.* | ***YES***  ***NO*** |
| *Benchmark control (i.e. in the dynamic midrange of the test system)*  *If yes, please specify the benchmark control.* | ***YES***  ***NO*** |
| 4.3 | *Are quality criteria for the test system (e.g. cell line, tissue model) being used and are they specified in the protocol? An example of quality acceptance criteria could be appropriate stratification and barrier function of a reconstructed human epidermis in each lot/batch released.*  *If yes, please describe these criteria (max. 150 words).* | ***YES***  ***NO*** |
| 4.4 | *Are there acceptance criteria for the data obtained for test items and controls and are they specified in the protocol?*  *If yes, please describe these criteria (max. 150 words).* | ***YES***  ***NO*** |
| 4.5 | *Does the test method require a procedure for deriving, on the basis of the raw data, the test method endpoint results?*  *If yes, please describe how the data are summarised and expressed (e.g. normalisation to negative control, derivation of a score value) (max. 150 words).* | ***YES***  ***NO*** |
| 4.6 | *Is there a prediction model/data interpretation procedure available and specified for translating the test method results (see 4.5) into predictions of human health, environmental and/or other biological effects (see also 6.1)?*  *If yes, please describe the prediction model (max. 150 words).* | ***YES***  ***NO*** |

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| **5.** | **Preliminary Assessment of the Reliability of the Test Method** | |
| 5.1 | *Was the within-laboratory reproducibility of the test method evaluated?*  *If yes, please describe how this was done and summarise the results (max. 150 words).* | ***YES***  ***NO*** |
| 5.2 | *Was the transferability of the test method to other laboratories evaluated?*  *If yes, please describe how this was done and summarise the results (max. 150 words).* | ***YES***  ***NO*** |
| 5.3 | *Was the between-laboratory reproducibility of the test method evaluated?*  *If yes, please describe how this was done and summarise the results (max. 150 words).* | ***YES***  ***NO*** |

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| **6.** | **Preliminary Assessment of the Predictive Capacity of the Test Method** | |
| 6.1 | *Does the test method allow for making predictions of human health, environmental and/or other biological effects (e.g. by predicting specific hazard classes) (see also 4.6)?*  *If yes, please describe the type of predictions that can be obtained (max. 150 words).* | ***YES***  ***NO*** |
| 6.2 | *Does the test method provide other or additional information (e.g. mode of action/mechanism of toxicity) that may be used for safety, efficacy or potency assessments?*  *If yes, please specify (max. 150 words).* | ***YES***  ***NO*** |
| *If one or both of 6.1 and 6.2 has been answered 'YES', please complete the following:* | | |
| 6.3 | *Indicate the number of test items used to draw conclusions on the prediction of human health, environmental and/or other biological effects, or on the mode of action/mechanism of toxicity. If possible, please indicate the chemical classes/organic functional groups covered (max. 150 words).* | |
| 6.4 | *Briefly specify which reference data (e.g. data from in vivo studies, in vitro studies, human data) were used to conclude on the prediction of human health, environmental and/or other biological effects, or on the mode of action/mechanism of toxicity (max. 150 words).* | |
| 6.5 | *If applicable, please provide a brief summary on the predictive capacity (i.e. specificity, sensitivity and overall accuracy) of the test method (max. 150 words).* | |
| 6.6 | *Are the raw data available for independent evaluation?* | ***YES***  ***NO*** |

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| **7.** | **References** |
| *Please add a list of relevant bibliographic (scientific) references (maximum 10).* |

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| **8.** | **Declaration on Confidential Information Contained Within the TPF** |

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| *Does this TPF contain information you consider as confidential (e.g. confidential business information, CBI)?* | | ***YES***  ***NO*** |
| *If yes, please indicate in which paragraph(s) such information has been entered and briefly describe the information:* | | |
| **Paragraph Number (e.g. 3.8)** | **Explanation as to Why the Information is Considered Confidential (max 100 words per paragraph)** | |
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| **9.** | **Test Method Submitter’s Request to EURL ECVAM** |

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| *Is your test method being submitted to EURL ECVAM for the purpose of being considered for its readiness to enter the EURL ECVAM validation process (i.e. prospective validation study, retrospective validation study, validation study based on performance standards or peer-review)?*  *Please specify your exact request to EURL ECVAM (max. 150 words).* | ***YES***  ***NO*** |

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| **10.** | **Privacy Statement** |

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| *By submitting the test presubmission form you confirm that you have read and understood the privacy statement* | ***YES***  ***NO*** |