OECD TEST GUIDELINES PROGRAMME

Standard Project Submission Form

If you have an interest in submitting a project proposal, please contact your National Coordinator first:

https://www.oecd.org/chemicalsafety/testing/national-coordinators-test-guidelines-programme.htm

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PROJECT OUTCOMES

☐ New Test Guideline

☐ Revised Test Guideline

☐ Deletion of an existing Test Guideline

☐ Guidance document

☐ Detailed Review Paper

☐ Other, please specify below

PROPOSED WORK PLAN and RESOURCE NEEDS:

1. Draft workplan for development of the proposal, including any need to establish Ad Hoc Expert Group and mode of meetings (face-to-face, teleconference; electronic discussion group). Indicate key milestones, including first and subsequent drafts of documents and timing of meetings.

2. Will additional information, including generation or collection of data, be required? If yes, please describe the anticipated process and timelines.

3. Indicate the estimated overall resource need (time/money) for member country / consortium and Secretariat

4. Is this proposal intended to replace an existing Test Guideline or lead to the deletion of an existing Test Guideline?

ESSENTIAL INFORMATION

In this section, please provide the information required by the Working Group of National Coordinators of the Test Guidelines Programme to assess the suitability of the project for the workplan of the Test Guidelines Programme

1. What is the existing or expected regulatory need/data requirement that will be met by the proposed outcome of the project? Please provide details below or as an attachment.

or as attachment No.__

2. How will the work contribute to further international harmonisation of hazard and risk assessment? Please provide details below or as an attachment.

or as attachment No.__

3. How will the proposed project address issues and /or endpoints which are of major human health or environmental concerns? If there are existing Test Guidelines or projects in the work plan of the Test Guidelines Programme covering the same endpoint, please refer to these and describe the added value and usability of the proposed new test method. Please provide details below or as an attachment.

or as attachment No.__

4. Will the project have general support from OECD member countries or is the outcome relevant for just one or a few member countries / stakeholders? Provide details of the countries and the rationale for this view below.

☐ Many countries ☐ A few countries ☐ Only for the submitting country

5. If the Test Guideline is not intended for general use, indicate if the Test Guideline would be intended for:

☐ Specific (limited) applications such as pesticide usage, or

☐ for specific classes of chemicals (e.g. surfactants) rather than for chemicals in general.

6. If the expected outcome of this proposal is a Test Guideline or a Guidance Document, provide information on the intended use, applicability and limitations of the test method.

7. Provide supporting information on the validation status (i.e. relevance and reliability) of the method. Principles for validation of test methods for OECD Test Guidelines are described in Guidance Document 34.

Provide justification and rationale for the test, including data.

If there are no or limited data available to support the reliability and relevance of the proposed test, indicate if validation work is included in the project.

If there is no need for validation, provide a detailed justification.

8. Describe if the test method includes components, equipment or other scientific procedures that are covered (or pending) by Intellectual Property Rights (IPR) (e.g., patents, patent applications, industrial designs and trademarks). Information should be provided on the overall availability of the IPR-protected components including whether they are commercially available or require a Material Transfer Agreement (MTA) or other licensing agreements. In addition, a description of the IPR-covered component/test system should be disclosed.

8.1 Nature of protected elements (e.g. reagent identity, cell line identity, specific process, etc.):

8.2 Form of protection (e.g. trademark, patent, etc.):

8.3 For users to access protected elements, please tick the relevant box(es):

☐ MTA required ☐ License requirement ☐ No agreement required

8.4 Are you providing the agreement document(s) referred to in 8.3 with the SPSF:

☐ Yes ☐ No If no, what's the reason?

8.5 How and where can users get access to protected elements?

8.6 Has any search for existing patent(s) possibly associated with this test method been performed (e.g. through patent search or Freedom-To-Operate search). If yes, what was the outcome?

<u>IMPORTANT NOTE:</u> Should the OECD and Expert Group working on the Test Guideline development discover that the information provided under Item 3 on IP elements be erroneous or be evolving in the course of the project, the project itself might be re-considered, suspended or cancelled.

9 Have Performance Standards been developed? ☐ Yes ☐ No ☐ N/A

ADDITIONAL INFORMATION

In this section please provide further information to allow the Working Group of National Coordinators of the Test Guidelines Programme to assess the suitability of the project for the workplan of the Test Guidelines Programme

1. If the expected outcome of the project proposal is a Test Guideline and is based on existing, regional or international documents such as guidelines, protocols or guidance material, please provide that information here or as an attachment.

or as attachment No.__

2. If Animal Welfare considerations are addressed in the project proposal, provide details below or as an attachment. Explain if the project is aimed at refining, reducing and/or replacing the use of animals.

If the project is not specifically developed for animal welfare purposes, indicate if the animal welfare considerations have been a component of the project proposal.

Indicate if animal welfare considerations are irrelevant to the project, for example for physico-chemical properties.

or as attachment No.__

3. Provide information on expected or possible resource savings in member countries as a result of this project.

4. If the expected outcome of the proposed project is a Guidance Document or Detailed Review Paper, will it be directly linked to the development of a particular Test Guideline or a series of Test Guidelines?

☐ Yes, it is the initial step in the development of a new or revision of existing Guidelines.

☐ Yes, additional guidance is needed for the most appropriate selection of the Guidelines on the subject.

☐ No, the guidance is on issues related to testing or the development of Test Guidelines in general.

There are ___ attachments added to this form.
