**OECD ADVERSE OUTCOME PATHWAY**

**Project Submission Form**

**If you require further information please contact the OECD Secretariat**

**Return completed forms to our generic account (env.tgcontact@oecd.org), and Nathalie Delrue (Nathalie.delrue@oecd.org)**

**PROJECT TITLE**

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**SUBMITTED BY (organisation/consortium/ agency,…)**

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**DATE OF SUBMISSION TO THE SECRETARIAT**

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**DETAILS OF PROJECT PROPONENT(S)**

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| **Country/Organisation:** |  |
| **Agency/ministry/Other:** |  |
| **Contact person(s):** |  |
| **Mail Address:** |  |
| **Phone:** |  |
| **Email:** |  |

**PROJECT CATEGORY**

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| Development of an AOP - applicable to a chemical category  Select the development tool to be used  AOP-Wiki  Effectopedia  Guidance document related to AOP development including its evaluation  Knowledge management tool for supporting AOP development including its evaluation  Other, please specify below |
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| *If other category, please specify:* | |

**BACKGROUND INFORMATION**

With this form, the proposer requests the inclusion of an AOP project proposal on the OECD AOP development work plan.

It should be noted that this submission can be made at any stage in the development of an AOP and is not a prerequisite to the development of an AOP in the wiki platform (see how to request author access to the AOP-Wiki at <https://aopwiki.org/>).

Before a decision is taken by the Extended Advisory Group on Molecular Screening and Toxicogenomics (EAGMST) on the inclusion of the AOP proposal in the AOP development work plan, regulatory bodies[[1]](#footnote-1) will be consulted in order to help assess the regulatory relevance of the proposal. This consultation will also raise awareness and encourage engagement of the regulatory community. It is thus important that the section on the regulatory relevance of the proposal at the end of the form be carefully addressed by the AOP proposer.

By including a project on the OECD work plan, EAGMST guarantees coaching support, leading to internal review (i.e. compliance check with [User’s handbook](https://one.oecd.org/document/ENV/JM/MONO(2016)12/en/pdf)/conventions). Inclusion on the work plan does not, however, guarantee that the AOP will subsequently be externally reviewed (i.e. scientific review), which depends on resource prioritisation, or that it will be endorsed.

**PROJECT DESCRIPTION**

**Please provide sufficient information to facilitate the review of the project submission by the OECD secretariat and the Extended Advisory Group with respect to its suitability to be included in the workplan of the AOP programme.**

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Note: For AOP Development projects please indicate the extent of the pathway to be described (i.e. the anchor points), the intermediate events that are likely to be addressed, the state of current development**,** the degree to which this pathway is already understood and described in the literature, and the expectation on the availability of evidence to support the AOP. Please provide references, links or attachments for supplementary information.

**FLOW DIAGRAM**

**In this section, please provide a flow diagram of the proposed AOP, including the MIE, KEs at the various stages (molecular interaction, cellular response, organ response) and the AO.**

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**REGULATORY RELEVANCE**

Proposers should indicate if and how the proposed AOPs are associated to any regulatory toxicological endpoints (e.g. acute or chronic toxicity, toxicity to reproduction, developmental neurotoxicity, non-genotoxic carcinogenicity, endocrine disruption etc.). Proposers will indicate what are the potential regulatory applications of the proposed AOPs. The following elements can be considered in addressing this section:

* + Is the project linking to ongoing or future projects in OECD such as Integrated Approach to Testing and Assessment (IATA) projects [[link to webpage](http://www.oecd.org/chemicalsafety/risk-assessment/iata-integrated-approaches-to-testing-and-assessment.htm) – see case study projects] or Test Guideline development [[Link to current OECD TGs](http://www.oecd.org/chemicalsafety/testing/oecdguidelinesforthetestingofchemicals.htm) - [Link to TG development workplan](http://www.oecd.org/env/ehs/testing/ENV_JM_WRPR_2019__TGP-work-plan.pdf)]? (if so, please describe)
  + Do the proposed AOPs complement an existing network of AOPs addressing a regulatory endpoint? (if so, please describe)
  + Do the proposed AOPs identify a regulatory gap, or lack of adequate testing methods and thus:
* Help identify candidate in vitro assay or battery of assays (if so, please describe)
* Help standardise testing for certain endpoints (if so, please describe)

Proposers should also mention if they are aware of any indications of commitment from any organisation (e.g. government/agency/academia) to support AOP development and eventual review.

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**PROJECT PLANNING**

**In this section, please provide an indication of when the project is likely to start and the expected duration. Please also make reference to any particular milestones or external factors that will influence project planning, and if the project is linked to programmes of particular organisations or consortia.**

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**COORDINATION OF OECD ACTIVITIES**

**AOP developers who submit a new AOP project proposal are invited to inform their National Coordinator of the Test Guidelines Programme.**

**Please tick this box if you have contacted your National Coordinators (**[**link to NC list**](https://www.oecd.org/env/ehs/testing/national-coordinators-test-guidelines-programme.htm)**) prior to submission of this form:**

1. Regulatory bodies meant are mainly the OECD Working Group of the National Coordinators of the Test Guidelines Programme (WNT) and the Working Party on Hazard Assessment (WPHA). [↑](#footnote-ref-1)