

**Animals in Science Regulation Unit (ASRU)**

Prospective Authorisation Form

December 2023

# Assessment of a Request for Prospective Authorisation of a Regulatory *In Vivo* Test

Applicant to complete sections 1-8 and submit to [ASRULicensing@homeoffice.gov.uk](mailto:ASRULicensing@homeoffice.gov.uk)

|  |  |
| --- | --- |
| **PPL Number** |  |
| **PPL Holder** |  |
| **Establishment Name** |  |

**Situation: What test/testing strategy is being requested, and why?**

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| ***Please ensure the test being requested and the type of product to be tested are named here.*** *E.g. The manufacturing process for agrochemical x has been altered, and the Japanese authorities require an in vivo test to be performed to re-authorise its use, on the basis that the new manufacturing process may result in a different purity/impurity profile.* |

**Regulatory requirement**

1. **Is the test/testing strategy being requested being conducted to satisfy a regulatory imperative?**

|  |  |
| --- | --- |
| Yes | Add any comments below then go to [question 2](#two). |
| No | Refuse permission on the basis that there is insufficient evidence that a regulator actually requires this test. Add any comments below then go to [Recommendation](#Recommendation)*.* |
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| *Is the test required by a regulator? Or does it form a critical part of a regulatory submission? Describe the evidence you have. Have similar products that have completed the authorisation process for the same regulator required the same test? If not, why is this product different, or what extra information will be gained?* |

**Duplication of data**

1. **Is scientifically satisfactory data already available that is satisfactory to the regulator in question?**

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| --- | --- |
| No | Add any comments below then go to [question 3](#three). |
| Yes | Refuse permission on the basis that data is already available that will satisfy the regulator in question. Add any comments below then go to [Recommendation](#Recommendation)*.* |
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| *Is the data already available scientifically satisfactory? If not, why not? Will the data satisfy the regulator in question?* |

**Scientific validity**

1. **What is the scientific question being posed?**

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| *Describe the scientific justification for using the proposed test.* |

1. **Will the test/testing strategy answer the scientific question being posed?**

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| --- | --- |
| Yes | Add any comments below then go to [question 5](#five). |
| No | Refuse permission on the basis that the test will not provide the scientific information required. Add any comments below then go to [Recommendation](#Recommendation)*.* |
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| *Comments as necessary* |

**Animal welfare**

1. **Is there a lower impact version of the testing strategy in use anywhere else worldwide?**

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| --- | --- |
| No | Add any comments below then go to [question 8](#eight). |
| Yes | Add any comments below then go to [question 7](#seven) |
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| *What evidence/assurances do you have that this is the case? Please ensure that any alternative tests are named or described here.* |

1. **Would this lower impact testing strategy provide a scientifically satisfactory outcome?**

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| No | The request is for the lowest impact test that is scientifically satisfactory. Add any comments below then go to [question 7](#seven). |
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| Yes | Refuse permission on the basis that the requested test is not the lowest impact test that will be scientifically satisfactory |
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| *If no – why not? Are you satisfied that it is really not scientifically possible to use the lower impact test? Refer to the scientific justification provided in questions 3 and 4.* |

**Harm Benefit Analysis**

1. **Define the harms**

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| *Animal numbers*   * *Consider the total animal use, including the use of animals should tests have to be repeated or validated*   *Animal experience and endpoints*   * *Including time-related endpoints and severity-related endpoints*   *Consider the likely and worst case scenarios and their probability.*  *Consider the experience of the team performing the test.* |

1. **Define the benefits**

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| *What is the need for the substance? What does it do? Are there other substances already available that satisfy this need? If so, why is this substance required?*  *Benefits to consider may be:*   * *New product meeting an unmet need* * *Better formulation or version of an existing product*   + *More effective/fewer unwanted effects*   + *Easier to use/will bring better compliance*   + *Cheaper/more accessible to vulnerable users* * *Adds to an existing product ensuring more secure supply* * *More efficient production than existing product (e.g. less impact on environment)* * *More efficient distribution than existing product (e.g. no cold chain required, local production means less impact on environment)*   *Consider the experience of the team performing the test and their culture of care.*  *Consider any benefits associated with the test itself e.g. better specificity/sensitivity.* |

------------------------------------------------- **For official use** ---------------------------------------------------

1. **Assessment of harms, benefits, and ethical considerations**

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| *Where there is a difference between the requested test and the lowest impact test in use elsewhere, there must be associated benefit commensurate with allowing the higher impact test for that jurisdiction.*  *The experience of the sponsor and the nature of their relationship with the organisation performing the test may be of relevance when assessing the reliability of the information provided.*  *The context of the regulatory requirement for the requested test may be relevant. For example, a disease outbreak in that particular country may indicate that the higher impact but more sensitive/specific test is necessary, and will afford better protection. Or if the population expected to use/be exposed to the product in that particular country is particularly high or sensitive, a lower sensitivity/specificity associated with the lower impact test may no longer be acceptable. Such contextual factors may not be known, but inspectors can use their professional judgement to infer such benefits associated with the test methodology itself, where appropriate. Inferred benefits such as these will necessarily carry a lower “weight” in the harm benefit analysis than those underpinned by evidence. The expected harm to protected animals in terms of pain, suffering, distress and lasting harm must be justified by the expected outcome, taking account of ethical considerations, the likelihood of producing satisfactory results and the expected benefit to humans, animals or the environment.* |

1. **Are the harms outweighed by the benefits?**

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| No | Refuse permission on the basis of an unfavourable harm benefit analysis. Go to [Recommendation](#Recommendation). |
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| Yes | Grant permission. Go to [Recommendation](#Recommendation). |
|

1. **Recommendation**

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| I recommend that permission for the testing outlined above is:  **Refused** on the basis: | | |
|  |  | that there is insufficient evidence that the regulator actually requires this test. |
|  |  | that data are already available that will satisfy the regulator in question. |
|  |  | that the test will not provide the scientific information required. |
|  |  | that the requested test is not the lowest impact test that will be scientifically satisfactory. |
|  |  | of an unfavourable harm benefit analysis. |

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| **Granted** using one of the mechanisms for granting authority outlined below. |

**The recommendation will be made subject to the following restriction(s)**

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| *Permission may be given for*   * *A one-off test,* * *Using the test for a defined period of time, or* * *Using the test for a defined number of animals/tests, or* * *The duration of the licence,* |

**Mechanism for granting authority**

The PPL holder has been advised that:

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|  | The test is legal under the existing authority of the PPL. |
|  | An amendment to an existing PPL is required in order to authorise the work described. |
|  | A new PPL will be required in order to authorise the work described. |

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| **ASRU Inspector:** |  |
| **Date:** |  |

Please send a copy of this completed form to the applicant and ASRU Licensing.