

Commission of policy advice from the Animals in Science Committee

Non-Technical Summaries and Retrospective Assessments

DATE:	21 November 2024
POLICY SUMMARY:	Non-technical summaries (NTS) and retrospective assessments (RAs) under the Animals (Scientific Procedures) Act 1986 (ASPA) are key for transparency on the use of animals in science and learning to support the 3Rs (replacement, reduction and refinement). This more detailed scope follows the commission to the Committee for advice on standards for NTS and RA content that will improve openness and transparency and support the science sector in implementation of the 3Rs more effectively in alignment with ASPA.

1. Policy issue

There is significant public interest in enhancing access to information on the use of animals in science and the Home Office is committed to transparency wherever possible.

The quality of Non-Technical Summaries (NTS') published on gov.uk¹ have been the subject of a number of published papers and reports which have highlighted areas for improvement. The Retrospective Assessments (RAs) can deliver transparency and enable greater learning about the use of animals in science licensed under ASPA². These documents are important as the Home Office does not routinely release information from project licences or applications as these are exempt from disclosure (see Section 24 of the Animals (Scientific Procedures) Act 1986).

The RAs can also show whether the objectives have been achieved and whether lessons can be learnt from the programme of work which may contribute to the further implementation of the principles of the 3Rs. They are now starting to be published on gov.uk³ and it is important that they are as effective as possible in implementing the 3Rs and driving leading practice.

Therefore, the Home Office seeks continuous improvements to the quality and utility of NTS' and RAs that will deliver the intent of ASPA in enabling increased transparency, create the opportunity for greater understanding of how animals are used in science and improve protections of animals in science.

2. Context

Non-Technical Summaries

What does the ASPA require for NTSs?

ASPA requires that an application for a project licence must be accompanied by a project summary using between 500 and 1,000 words written in non-technical terms and which can be understood by a non-scientist. The summary must:

- describe the proposed programme of work and state the objectives of the programme;
- state the types of animal and the estimated number of each type that will be used;
- predict all of the likely harms to the animals that will be caused and the likely benefits that will be gained by carrying out the programme of work; and
- demonstrate how the principles of replacement, reduction and refinement will be complied with throughout the project;

It must not contain the following:

- information of a confidential nature
- information the publication of which may lead to the infringement of any person's intellectual property rights
- names and addresses

¹ www.gov.uk/government/collections/animals-in-science-regulation-unit#non-technical-summaries

² www.gov.uk/government/publications/consolidated-version-of-aspa-1986

³ www.gov.uk/government/collections/animals-in-science-regulation-unit#non-technical-summaries

When a project licence is granted, a copy of the project summary that will accompany the application must be published. However, before doing so, it will need to be altered to include information on whether and when the programme of work should be retrospectively assessed; and include any appropriate additional information in order to assist a person who reads the summary. (ASPA 5A (1), (2), (3) and (5D) 6 and 7))2⁴.

The Home Office Regulator (ASRU), via assessment by an Inspector, assesses the NTS against standards. Authorisation for a project licence will not be given until the standards (and those required throughout the rest of the licence application) are met.

What NTS guidance is currently available to support project licence applicants?

The Animals in Science Regulation Unit (ASRU) Guidance Note for Project Licence Applications sets out requirements for NTS⁵ which all establishments must follow.

Externally, Understanding Animal Research have published a guide to support researchers writing non-technical summaries⁶ and The European Animal Research Association working group on non-technical summaries produced a guidance document to improve the language and understanding of NTS for the general public⁷.

Publication of Current NTS

In April 2024 ASRU published that they had amended how NTS are published to improve accessibility and ensure a complete record is kept. NTS are now presented in two documents: one for those that do not require a retrospective assessment and another for those that require a retrospective assessment.

ASRU now publishes NTS routinely every 3 months which can be found here: https://www.gov.uk/government/collections/animals-in-science-regulation-unit#non-technical-summaries

Retrospective Assessments

What does the ASPA require for RAs?

Any project licences authorised after 1 January 2013 using non-human primates, cats, dogs and equidae and all those involving procedures classified as severe must be assessed retrospectively. In addition, all project licences for education, training and those authorising the use of endangered animals will be assessed retrospectively.

Consideration is given to whether other projects should be assessed retrospectively. This may also be reconsidered during the life of a project. The following information is taken into account when considering if a retrospective assessment is required:

- the number and type of procedures to be used;
- the number and species of animals to be used;
- the nature of the programme of work and its objectives; and
- whether the project raises any important animal welfare or ethical concerns, novel or contentious issues, or societal concerns.

⁴ <u>www.gov.uk/government/publications/consolidated-version-of-aspa-1986</u>

⁵ www.gov.uk/guidance/animal-research-technical-advice#guidance-notes-for-project-licence-applications

⁶ www.understandinganimalresearch.org.uk/news/guidance-for-writing-a-nts

⁷ https://static.wixstatic.com/ugd/e7d918 df60c32bacc94513a9d30ea827673243.pdf

If a project licence is to be retrospectively assessed, the project licence holder is required to provide information to their establishment's Animal Welfare and Ethical Review Body (AWERB) at the time the retrospective assessment is due to be carried out. The information provided must include an updated non-technical summary and enable the AWERB to also consider:

- whether the programme of work has been carried out;
- whether the objectives of the programme of work have been achieved;
- the amount of harm caused to animals by the carrying out of the programme of work (including the number of animals subjected to regulated procedures as part of the programme of work, the species of animals subjected to those procedures and the severity of those procedures); and,
- whether any lessons can be learnt from the programme of work which may contribute to the further implementation of the principles of replacement, reduction and refinement.

The AWERB will then retrospectively assesses a project, including the harms and benefits and on completion (normally within three months of the due date), will submit the AWERB's conclusions, together with the updated non-technical summary agreed with the AWERB, in order that an inspector can complete the assessment. (ASPA 5B (3), (7), 5D (5), (7), (5F)² and ASPA Guidance 5.17, 5.18.10, 10 (4), (5) and 12 (3)⁸). This will then need to be published by the Regulator.

3. Evidence

Papers published on NTS have included the following findings. This is not intended to be a comprehensive picture of the available evidence.

- a. Language needs to be more understandable to the lay person^{9,11,12}.
- b. Shortcomings in NTS, including that they are deficient in the description of what is being done to the animal and what they might experience ^{10,11,12}.
- c. NTS should include sufficient detail of expected harms, especially of severe protocols or potentially controversial protocols⁹.
- d. Aims and objectives should clearly provide a summary of the programme of work, including species to be used⁹.
- e. NTS should explain clearly the various steps taken to replace, refine and reduce the use of animals in lay term, with evidence of this^{9,10}.
- f. Benefits should be those expected of the programme of work, wider benefits should be described in realistic terms⁹.
- g. NTS are seen as a statutory requirement instead of an opportunity to provide a way of engaging interested people with the research projects taking place⁶.

06/CFI%20UK%202020%20NTS%20report%20April%202023.pdf

⁸ www.gov.uk/guidance/guidance-on-the-operation-of-the-animals-scientific-procedures-act-1986#guidance-on-the-operation-of-aspa

⁹https://assets.publishing.service.gov.uk/media/5f7203f5d3bf7f47ab494323/Report_of_the_Licence_A nalysis Subgroup.pdf

¹⁰ Taylor, K., Rego, L. and Weber, T. (2018) "Recommendations to improve the EU non-technical summaries of animal experiments", ALTEX – Alternatives to animal experimentation, 35(2), pp. 193–210. doi: 10.14573/altex.1708111

¹¹ www.gov.uk/government/publications/asc-and-awerb-hub-workshop-report-october-2023

¹² https://crueltyfreeinternational.org/sites/default/files/2023-

A batch of RAs have recently published therefore there is limited review of their quality available. However, we are keen to look at these now so that future RAs can be as effective as possible.

4. Evidence sought from the Animals in Science Committee

The Government wishes to receive advice from the Committee so the Regulator may be provided with standards applicable to the NTS and RA content that support openness and transparency and are in alignment with ASPA.

The Committee may wish to make other recommendations as it sees appropriate.

The Committee is asked to provide written advice on the question set out above by 30 September 2025.

5. Process

How will the Committee provide advice?

The Committee will provide written advice to the UK Government in line with its statutory remit, as set out in ASPA Section 20:

- (1) The Committee must provide advice to the Secretary of State and the Animal Welfare and Ethical Review Bodies on such matters relating to the acquisition, breeding, accommodation, care and use of protected animals as the Committee may determine or as may be referred to the Committee by the Secretary of State.
- (2) In its consideration of any matter the Committee shall have regard both to the legitimate requirements of science and industry and to the protection of animals against avoidable suffering and unnecessary use in scientific procedures.
- (3) The Committee must take such steps as it considers appropriate to **ensure the sharing of best practice** in relation to the acquisition, breeding, accommodation, care and use of protected animals.

In developing advice, the Committee will wish to gather relevant evidence by engaging with relevant stakeholders concerned with science and industry, animal protection, and regulated establishments.