

## **Referral of applications to the Animal Procedures Committee (APC) - ASPI/APLS/APC Guidance.**

**This document has been prepared to clarify the administrative and other processes to be followed when casework is referred to the Animal Procedures Committee for advice.**

### **Background**

It is the duty of the Animal Procedures Committee (APC) to advise the Secretary of State (SoS) on such matters concerned with the Animals (Scientific Procedures) Act 1986 (ASPA) and his functions under it as the APC may determine or as may be referred to the APC by the SoS. In its consideration of any matter the APC 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.

The SoS has agreed to refer selected project licence (PPL) applications to the APC for advice, in addition to that given by the Animals (Scientific Procedures) Inspectorate (ASPI) (and on occasion independent external assessors), on whether and on what terms authorities should be granted. The APC has established a Subcommittee to act on its behalf in relation to such referrals.

This document clarifies the process for such referrals, including the relevant responsibilities, with the aim of ensuring minimal unnecessary delay in the processing of relevant applications.

Since January 2005, the four categories of applications for referral to the APC are:

1. any project involving the proposed use of wild-caught non-human primates;
2. any project involving the proposed use of cats, dogs, equidae or non-human primates in protocols of substantial severity;
3. any project which involves a substantial severity banding, or major animal welfare or ethical implications, involving xenotransplantation of whole organs, chronic pain models, or study of the central nervous system;
4. applications of any kind raising sufficiently novel or contentious issues, or giving rise to serious societal concerns, (for example, any application involving the genetic modification of non-human primates or embryo-aggregation chimaeras involving dissimilar species.)

Categories 1, 2 and 3 above are clear cut, and category 4 requires that an informed decision is made as to whether referral is appropriate, in the first instance by those (ASPI) advising and those (ASPD) acting on behalf of the SoS.

## **Identification of applications for referral to the APC**

The agreed categories for referral are listed in Section 15 of the project licence (PPL) form of application. However, an Inspector's professional knowledge and experience are required to determine whether or not the application may fall within the category 4 referral listed above.

## **Role of the Inspector**

### Assisting the Animal Procedures Licensing Section (APLS)

ASPI should:

- Identify applications for potential referral to the APC as early in the assessment process as possible, seeking advice from the Chief Inspector (CI) if necessary.
- Identify all the relevant sections of the application, and other materials, that should be provided to the APC to ensure a thorough understanding of the issues.
- Provide a brief summary of the proposal, the reasons for referral, and any specific questions to be addressed by the APC.
- Confirm that APLS has prepared the correct dossier of material for referral to the Committee.
- After advice has been received from the APC, promptly to advise the Head of APLS on the practicability and the implementation of the APC's advice, critiquing and revising any preliminary ASPI advice if necessary, and to minute the file accordingly.

All information to be provided to the APC should be channelled by the Inspector through the CI who will initiate the referral process via APLS.

### Assisting the APC

- The Inspector is normally invited and encouraged to attend the meeting of the APC considering the application.
- The Inspector may provide relevant information regarding local conditions at the establishment where the intended project is to be carried out, for example facilities available, management systems and controls, etc.
- The Inspector is expected to provide technical advice on ASPA and its interpretation in relation to the application, not to defend the application.
- Other Inspectors, including the CI and those with special interest in particular aspects of the application, are normally also invited to attend the meeting of the APC.

## **Role of APLS**

### Assisting ASPI

- Ensure the referring file minute alerts the Inspector to the need for referral to the APC from information provided in Section 15 of the PPL application.
- In rare cases APLS will ask ASPI to (re)consider projects that were not initially identified by ASPI as needing referral to the APC.

### Assisting the APC

- Advise the APC Secretariat in a timely manner of potential referrals
- Prepare and supply referral documents for the APC explaining the background for referral and setting out the salient points and, where appropriate, the key issues that may need to be considered.
- Copy and collate the relevant information from the PPL application to be given to the APC.

### Assisting the Secretary of State

- Liaise with ASPD on possible additional novel or contentious applications meriting referral to the Committee.
- Consider the advice received from ASPI and the APC and take appropriate action with the minimum delay.

## **Role of the APC**

Mindful of the Home Office Better Regulation initiatives, the APC has agreed to define for ASPI and the scientific research community, and to periodically review, the particular requirements, with regard to the type of information and the level of detail, expected to be included in the categories of PPL applications that are referred.

- The APC will deal with all applications referred to it expeditiously, to the previously agreed indicative times.
- Advice proffered by the APC to the SoS will be clear and practicable, and the Secretariat will communicate that advice to APLS staff within 30 days of referral.

## **Monitoring and Review of Guidance**

The CI, Head of ASPD, Head of APLS, Chair of the APC and (if different) Chair of the APC Subcommittee will jointly monitor the implementation of this guidance.

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