



Understanding Animal Research

Response to ASC NHP recommendations consultation

Thank you for the opportunity to comment on the Animals in Science Committee's recommendations on the supply and use of non-human primates (NHPs) in scientific procedures.

Understanding Animal Research is membership organisation, supported by companies and institutions from across the spectrum of biomedical science in the UK. A small number of our members use NHPs in scientific procedures. Some of these organisations source their NHPs from UK breeding establishments while others need to import NHPs from overseas suppliers.

We are aware that our members that use NHPs in scientific procedures are responding to this consultation exercise and will be able to provide specific details and evidence in answer to the questions. We have therefore not answered all your questions in this response. Instead, we have noted points that our members have raised with us and which we hope will be helpful in answering your questions.

Overall, we fully support the ASC's recommendations that all NHPs used in scientific procedures should eventually be sourced from self-sustaining colonies and should preferably be F2 or above. We agree that F0 NHPs should not be used in research in the UK, unless there is scientific justification.

We agree that overseas breeders should be encouraged to set up new self-sustaining colonies to supply the UK market, and we recognize that the UK is in competition with other areas of the world for the available supply of NHPs. We therefore believe that any policy changes must encourage overseas breeders to view the UK as an attractive market and incentivize them to breed NHPs for use in the UK. Unless the breeders are prepared to make the changes required, the unintended consequences of changes in policy could be that those breeders simply stop supplying to the UK and concentrate on supplying larger markets with fewer regulatory requirements.

Generational status definitions

We welcome the move to make generational status definitions consistent across old world and new world NHPs. We also agree with the proposed definition of F1.

The definition of F2 is, however, potentially problematic since colonies are likely to include F0 and F1 males. Unless breeding can be arranged and monitored to the extent that it is certain which male fathered the offspring, it could be difficult to state categorically the generational status of the father and therefore of the offspring. Maintaining the previous situation where the mother's generational status defined the status of her offspring would avoid this issue. We would also suggest that if new self-sustaining colonies are to be created and closed from a set date, as recommended by the ASC, then being able to differentiate between the offspring of F0 and F1 males is less of a critical issue, since F1 animals from self-sustaining colonies are acceptable.

Self-sustaining colony status

We agree that overseas breeders should be encouraged to set up new self-sustaining colonies to supply the UK market, and that these should be allowed to be defined as self-sustaining as long as they are permanently closed on a set date and no wild-caught animals are introduced after the closure date.

We believe, however, that in order to encourage breeders to set up these new colonies, they should be allowed more time. As we understand it, it can take time for colonies to 'settle down' after new animals are introduced. Breeders should be allowed several months of 'trial and error' in creating new colonies to ensure that the animals can live together happily, and should be able to swap animals between colonies if necessary. However, we suggest that the time limit for new self-sustaining colonies to be permanently closed should be agreed with breeders.

Status of NHPs that can be used in scientific procedures

We agree with the aim that all NHPs used should be F2 or above, or from a self-sustaining colony. We understand, however, that most NHPs used in scientific procedures are around two years old. The gestation period for macaques is around six months. Therefore, an exemption period of two years is not long enough to allow breeders to set up a new, closed colony and produce a first generation of F1 animals, let alone any F2 animals. We therefore suggest that the exemption period is either increased to at least three years, or that the current situation is reviewed after the suggested two years, and further decisions taken at that time as to how long the exemption period may need to be extended.

The exemption to allow breeders to sell F1 animals not from self-sustaining colonies to the UK while new self-sustaining colonies are being created is vital. We believe, however, that it should either be for longer than two years, or reassessed at the end of two years. The reason for this is that the preclinical toxicology studies that these NHPs are used for are often booked several years in advance. If F1 NHPs not from self-sustaining colonies are not allowed to be imported after November 2024, and F1 animals are not yet available from the new self-sustaining colonies, then studies booked for 2025 and 2026 will not be able to take place in the UK.

Potential steps to ensure security of supply of cynomolgus macaques

At present, the UK uses in excess of 2,000 NHPs for regulatory pre-clinical toxicology studies each year. The animals used in these studies are almost exclusively cynomolgus macaques sourced from overseas. The UK's NHP breeding establishments currently produce a few hundred animals each year, mainly used in academic and public health research. We would encourage significant expansion of the UK colonies to produce enough animals to ensure a large enough supply to meet the needs of all UK pre-clinical toxicology testing. This would be a long-term project: we understand it would potentially take up to ten years to breed enough animals to be able to sustain a supply of 2,000 animals a year. To achieve this would require a lot of space, a lot of money and probably the collaboration of the overseas breeders. We believe the animal welfare benefits of reduced transportation time, together with the security of supply, would justify the required investments of time and money.

The other side of the equation is reducing demand for NHPs. Any study involving NHPs is already highly regulated. The Home Office Animals in Science Regulation Unit should continue to ensure that the 3Rs are fully considered and applied in all studies involving NHPs. Regulators should also be encouraged to review their requirements for the numbers of NHPs needed in preclinical studies.

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